GLOBAL COSMETICS RISK ASSESSMENT MASTER INDEX

CREAMS | SHAMPOOS | SUNSCREENS | PERFUMES | HAIR COLOUR | MAKEUP | ORAL COSMETICS

ALL COSMETIC PRODUCTS • RAW MATERIALS • MANUFACTURING • QC / MICRO • QA • EHS

ISO 22716 | INDIA COSMETICS RULES 2020 | EU 1223/2009 | US MoCRA | UK / ASEAN

Document code	ISHA-COS-RA-MASTER-001
Revision / issue date	Rev 00 | 05 November 2026
Equipment, process and system topics	940 distinct topics
Proposed micro-level risk scenarios	2,820 in companion scored Excel register
Functional areas / departments	42
Register status	Proposed screening inventory - site applicability and approval required

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EXECUTIVE PURPOSE & APPLICABILITY

This master index is a site-applicability reference for cosmetic product safety, equipment, raw materials, formulation, production, packaging, warehouses, laboratories, process water, maintenance, ISO 22716 GMP controls, regulatory compliance, consumer adverse events, contract manufacturers and occupational/environmental hazards. Covered products include creams, lotions, shampoos, soaps, toothpastes, sunscreens, perfumes, hair dyes, aerosols, nail polish, serums, makeup, eye cosmetics, powders, wipes and botanical/baby-care products.

The companion Excel workbook contains three differentiated proposed micro-level failure scenarios per assessment topic. These are independent screening prompts, not findings at a real facility. Real product risk must reflect intended use, consumers (especially infants / eye / mucosal users), local legal classification, exposure, formulation, packaging and verified controls. Product-safety acceptance is not decided by FMEA RPN alone.

ASSESSMENT METHOD & QUALITY / SAFETY BOUNDARIES

1. Determine the cosmetic, drug/OTC or other legal classification of each product for each market before assessing formula, claims, labeling and manufacturing license.

2. Define intended-use exposure, target population, allergens, irritancy, toxicology, preservative effectiveness, ingredient purity, packaging migration and in-use contamination pathways.

3. Conduct process FMEA / HACCP / contamination-risk assessment for equipment and operations, with measured evidence and independent quality/safety approvals; adapt scoring to a documented company scheme.

4. Product safety assessment (such as EU CPSR) must independently support consumer safety: FMEA Risk Priority Number is a screening/prioritization aid, not an approved safety decision.

5. Use ISO 22716 for cosmetics production, control, storage and shipment. Research & development and occupational / environmental risk require separate appropriate frameworks.

6. For water-containing products, evaluate microbial risk and preservative challenge efficacy with applicable ISO 17516, ISO 11930 and ISO 29621; avoid blanket testing or low-risk exemptions.

7. For sunscreen and claims-sensitive products, verify sunscreen legal status and claim evidence separately in each target market. For US markets, sunscreen is generally a drug.

8. Assess flammable alcohol/aerosols, nail solvents, caustics, persulfates and powder hazards through independent EHS studies and legally required control programs.

9. For each site-applicable risk record: enter identified equipment, existing safeguards, risk assessment scores, action owner, verification evidence, residual acceptability, QA / safety sign-off and review trigger.

REGULATORY ALIGNMENT AND MARKET-SPECIFIC EXCEPTIONS

The core cosmetics-specific framework includes ISO 22716:2007, India Cosmetics Rules 2020 (including licensing, labeling and applicable Ninth Schedule/BIS standards), EU Regulation 1223/2009 as amended, UK GB cosmetics obligations, US FDA MoCRA and ASEAN Cosmetic Directive/GMP. Product safety and technical methods include applicable ISO 11930, ISO 17516, ISO 29621 and sun protection test standards. Country- and category-specific obligations must be rechecked against current amendments before use.

Critical classification note: Do not automatically apply pharmaceutical Schedule M, sterile medicinal GMP, US 21 CFR 210/211 or clinical-trial Schedule Y to ordinary cosmetics. Conversely, products with sunscreen, medical, treatment or drug claims may be regulated as medicines/OTC drugs in some markets. EU fragrance allergen labeling amendments have implementation dates; verify all current ingredient and labeling restrictions before approval.

MASTER FUNCTIONAL COVERAGE

Function / department	Topics	Risk scenarios
Aerosols / Deodorants / Foam	21	63
Analytical Development / Method Transfer	20	60
Baby Care / Sensitive Skin / Vulnerable Users	16	48
Bar Soap / Syndet / Saponification	20	60
Cleaning / Hygiene / Sanitation	28	84
Computer Systems / Data Integrity	21	63
Contract Manufacturing / Private Label	16	48
Creams / Lotions / Emulsions	22	66
Distribution / Logistics / Sales	18	54
EHS / Occupational Safety / Environment	29	87
Engineering / Maintenance / Utilities	30	90
Eye Cosmetics / Mascara / Eyeliner	18	54
Facility Design / HVAC / Hygiene Zoning	20	60
Fragrance / Flavor / Color Compliance	18	54
Hair Color / Bleach / Straighteners	26	78
Herbal / Natural / Organic Cosmetics	16	48
Human Resources / Training / Administration	17	51
Innovation / Product Transfer / Launch	14	42
Makeup / Foundation / Lip Cosmetics	20	60
Microbiology / Preservation Efficacy	30	90
Nail Polish / Removers / Nail Products	16	48
Packaging / Labeling / Filling	31	93
Perfume / Body Mist / Cologne	20	60
Post-Market / Cosmetovigilance	22	66
Powders / Talc / Dry Cosmetics	20	60
Procurement / Supplier Quality	18	54
Product Safety / Toxicology	28	84
Production / Shared Process Equipment	34	102
Quality Assurance / Cosmetics QMS	28	84
Quality Control / Physicochemical Testing	30	90
Quality Risk Management / QA	20	60
Raw Materials / Ingredient Specifications	30	90
Regulatory Affairs / Market Compliance	29	87
Research & Development / Formulation	24	72
Serums / Gels / Actives	18	54
Shampoos / Face Wash / Body Wash	20	60
Sunscreens / UV Protection	22	66
Toothpaste / Tooth Powder / Mouth Products	18	54
Validation / Qualification / Calibration	26	78
Warehouse / Material Control	27	81
Water Treatment / Process Water	24	72
Wet Wipes / Mask Sheets / Pads	15	45

REGULATORY REFERENCE KEY

Code	Regulatory / guidance reference	Intended scope / applicability note
ISO22716	ISO 22716:2007, Cosmetics GMP	Cosmetics production, QC, storage, shipment; excludes personnel and environmental safety and R&D scope
INDCOS	India Cosmetics Rules 2020, amended	Cosmetic manufacturing/license COS-8/COS-9, labeling, ingredient and finished product standards, BIS Ninth Schedule
INDFAQ	CDSCO cosmetics FAQ / licensing	Form COS-5, COS-6 and licensing; new cosmetics permissions where relevant
EU1223	EU Regulation (EC) 1223/2009 as amended	CPSR, PIF, RP, ingredient restrictions, labeling, notification and serious undesirable effects
EUALG	EU Regulation 2023/1545 fragrance allergen labels	Allergen declarations and phased EU new-placement / stock transition dates
MCRA	US FDA Modernization of Cosmetics Regulation Act (MoCRA)	US facility registration/product listing and safety substantiation, contact and serious adverse events as applicable; exemptions
FDAOTC	US FDA cosmetics vs drug/OTC classification	Sunscreen, anti-dandruff, acne / drug claims may be drug or combination products; determine classification
UKCOS	UK GB cosmetics safety, Responsible Person and SCPN	GB PIF, safety report, ingredient labeling, notification and incident report; NI differs
ASEAN	ASEAN Cosmetic Directive and guidelines	ASEAN GMP, safety assessment, product information file, notification, claim and ingredient controls
ISO11930	ISO 11930:2019/Amd1:2022 preservation efficacy	Challenge-test and microbiological risk assessment methods for antimicrobial protection
ISO17516	ISO 17516:2014 cosmetics microbiological limits	Microbiological quality and specified organism limits, subject to updates and product risk
ISO29621	ISO 29621:2017 microbiologically low-risk cosmetics	Guidance to identify low microbiological risk products rather than blanket exemptions
ISO24444	ISO 24444:2019 SPF in vivo determination	SPF method where relevant and product legal status permits cosmetic route
ISO24443	ISO 24443:2021 UVA in vitro protection	In vitro determination of sunscreen UVA photoprotection
ISO16128	ISO 16128 guidance on natural/organic ingredient definitions	Terminology/criteria for natural and organic ingredients; not a stand-alone certification
EHS	Applicable worker chemical, fire, effluent and waste laws	EHS risk assessment separately from cosmetic GMP; local permissions and substance specifics

Official URLs for all references are available in the REGULATORY SOURCES worksheet of the Excel workbook.

01 | AEROSOLS / DEODORANTS / FOAM

21 distinct assessment topics • 63 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
AERO-001	Aerosol can design qualification	pressure rating and compatibility	can rupture under use
AERO-002	Aerosol can lining evaluation	corrosion resistance and migration	leachables or structural damage
AERO-003	Aerosol propellant blend verification	gas ratios and contaminants	incorrect pressure and exposure
AERO-004	LPG propellant storage area	flammable vapor controls	flash fire or explosion
AERO-005	Propellant feed line integrity	tightness and leak detection	flammable release into production
AERO-006	Aerosol can filling mass	liquid concentrate and gas ratio	underfilled/overpressured can
AERO-007	Aerosol crimping tool setup	curl dimensions and seal	propellant leakage
AERO-008	Aerosol valve fitting	component lot and actuator compatibility	spray failure or leak
AERO-009	Aerosol leak bath / detector	test sensitivity and recorded acceptance	leaking can released
AERO-010	Aerosol pressure test sampling	representativeness and acceptance	unsafe pressure not detected
AERO-011	Aerosol hot water bath safety	water temperature and thermal stress	can expansion/rupture
AERO-012	Aerosol spray pattern qualification	particle size and spray direction	poor use or inhalation issue
AERO-013	Aerosol flammability label check	warnings and use instructions	consumer ignition injury
AERO-014	Anti-perspirant metal salt concentration	market active status and assay	irritation or incorrect legal classification
AERO-015	Roll-on deodorant filling	container seal and microbial risk	contamination from roller contact
AERO-016	Deodorant stick wax processing	cooling and ingredient dispersion	grainy or breakable stick
AERO-017	Foam pump compatibility	surfactant, elastomer and dispensing force	unreliable output and contamination
AERO-018	Aerosol batch line clearance	previous can and label components	mislabelled pressurized product
AERO-019	Compressed gas storage inspection	cylinder restraints and leak safety	physical/worker injury
AERO-020	Spray dryer perfume capsule handling	powder dust and solvent control	flammable powder exposure
AERO-021	Aerosol transport classification	dangerous goods and heat exposure	incident during shipment

02 | ANALYTICAL DEVELOPMENT / METHOD TRANSFER

20 distinct assessment topics • 60 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
ADL-001	Analytical specification design	critical limits by product category	insufficient finished product control
ADL-002	Preservative content method	matrix extraction and analytical sensitivity	underpreserved product accepted
ADL-003	Fragrance marker assay	volatile loss and matrix interference	wrong fragrance content accepted
ADL-004	UV filter assay development	extraction and chromatography separation	incorrect sunscreen actives
ADL-005	Heavy metal method development	digestion recovery and matrix blank	toxic contaminant undetected
ADL-006	Nitrosamine method development	trace sensitivity and artifact suppression	false negative carcinogen impurity
ADL-007	Formaldehyde determination	free versus releasable fractions	unsafe exposure understated
ADL-008	1,4-dioxane method development	trace GC method and recovery	uncontrolled process byproduct
ADL-009	Microbial test neutralization	preservative carryover and suitability	false negative bioburden result
ADL-010	In-use microbiological assessment	recontamination and repeated opening	consumer contamination pathway missed
ADL-011	Dispersed phase particle sizing	method resolution and sampling	unstable particulate texture missed
ADL-012	Rheology curve method transfer	spindle, temperature and shear conditions	noncomparable viscosity release
ADL-013	Colorimetry method qualification	lighting and delta-E tolerance	nonuniform shade release
ADL-014	SPF testing route selection	applicable market and method standard	unsupported sunscreen protection claim
ADL-015	UVA protection assessment	wavelength method and acceptance criterion	unsubstantiated UVA protection
ADL-016	Fragrance allergen analytical screening	analyte panel and detection threshold	incomplete allergen declaration
ADL-017	Microbial challenge method protocol	inoculum and interval controls	invalid PET result
ADL-018	Stability indicator method selection	chemical and physical markers	degradation not detected
ADL-019	Laboratory method transfer	interlaboratory reproducibility and reporting	false disposition after transfer
ADL-020	Reference materials qualification	traceable calibrants and purity	biased quantitative results

03 | BABY CARE / SENSITIVE SKIN / VULNERABLE USERS

16 distinct assessment topics • 48 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
BABY-001	Infant skin product exposure assessment	higher surface-to-weight and skin barrier	underestimated ingredient dose
BABY-002	Baby powder inhalation risk	particle size and method of application	respiratory exposure in infants
BABY-003	Baby cream preservative challenge	skin contact and repeated jar use	microbial growth with higher impact
BABY-004	Baby wash eye irritation testing	contact exposure and mildness	eye injury during bathing
BABY-005	Baby lotion fragrance restriction	sensitizers and formulation policy	allergic reaction in infants
BABY-006	Baby wipe lotion stability	preservative and pack open frequency	microbial spoilage and rash
BABY-007	Diaper-area balm compatibility	barrier and occlusion	irritation or under-tested exposure
BABY-008	Sensitive-skin hypoallergenic claim	clinical/technical support and definition	misleading allergy assurance
BABY-009	Fragrance-free claim verification	masking fragrance and raw impurity	false fragrance-free label
BABY-010	Noncomedogenic claim support	test design and target population	unsubstantiated acne-related claim
BABY-011	Dermatologically tested claim evidence	study protocol and representativeness	misleading assurance
BABY-012	Children face paint colorant screen	approved body-area pigments and impurities	toxic or ocular exposure
BABY-013	Pediatric hand/face wipes ingestion risk	wet wipe handling and preservative	accidental oral exposure
BABY-014	Products for mucous membrane contact	microbiological and toxicological evaluation	infection or local irritation
BABY-015	Baby product packaging child access	sharp edges, choking detachable components	mechanical injury
BABY-016	Sensitive skin stability after contamination	preservative and in-use stress	compromised product protection

04 | BAR SOAP / SYNDET / SAPONIFICATION

20 distinct assessment topics • 60 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
SOAP-001	Soap kettle caustic charging	alkali strength and splash control	high alkalinity and worker injury
SOAP-002	Oil/fat feed formulation	saponification value and quality	free alkali or rancid soap
SOAP-003	Saponification temperature	reaction conversion and residence time	unreacted caustic/fatty acid
SOAP-004	Salt graining operation	brine purity and separation	unstable base or contaminants
SOAP-005	Glycerin recovery stream	mass balance and chemical segregation	uncontrolled composition
SOAP-006	Soap noodle receipt	moisture and grade	bar cracking or incorrect formulation
SOAP-007	Sigma mixer / amalgamator	homogeneity and foreign material	perfume/color nonuniformity
SOAP-008	Soap refining mill	roll gap and shear	grit or damaged texture
SOAP-009	Vacuum plodder	vacuum and extruder die cleanliness	air pockets and foreign bodies
SOAP-010	Soap billet cutter	weight and cutter integrity	wrong weight or metal debris
SOAP-011	Soap stamper and mold	pressure, cleanliness and alignment	cracks, mixed brand embossing
SOAP-012	Soap conditioning chamber	temperature and RH	bar sweating or deformation
SOAP-013	Soap curing/drying	moisture endpoint and shrinkage	unstable net weight
SOAP-014	Syndet bar binder mixing	binder plasticity and moisture	friable or defective bars
SOAP-015	Syndet extrusion	bar temperature and die wear	contamination or texture defects
SOAP-016	Soap pH/free alkali testing	accurate titration and limits	skin burns from excess alkali
SOAP-017	Soap fragrance loss control	volatile retention and heat	off-odor consumer complaints
SOAP-018	Soap wrap sealing	integrity and batch coding	moisture uptake and traceability loss
SOAP-019	Toilet soap pigment uniformity	milling and dosing	visual nonuniformity or staining
SOAP-020	Bar soap dust handling	dust collection and housekeeping	respiratory exposure and contamination

05 | CLEANING / HYGIENE / SANITATION

28 distinct assessment topics • 84 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
CLN-001	Cleaning master plan	equipment risk ranking and inspection	uncontrolled cleaning scope
CLN-002	Worst-case soil selection	pigments, oils, preservative and fragrance	residue missed for difficult product
CLN-003	Manual cleaning tools qualification	dedicated brushes and material compatibility	soil retained or fibers shed
CLN-004	Rinse-water suitability	microbial and chemical quality	postcleaning contamination
CLN-005	Detergent concentration control	dose, contact time and rinsability	cleaning inefficiency or residues
CLN-006	Sanitizer concentration control	active concentration and exposure time	microbial survival or chemical residue
CLN-007	Cleaning agent rotation	site flora and compatibility evidence	insufficient control of repeated isolates
CLN-008	Equipment cleanliness swabbing	swab recovery and sampling locations	false clean evidence
CLN-009	Clean-hold-time assessment	storage conditions and closure	recontamination before next campaign
CLN-010	Dirty-hold-time assessment	soil hardening and biofilm formation	reduced cleaning effectiveness
CLN-011	Allergen / fragrance changeover cleanup	residue acceptance by exposure	undeclared allergen carryover
CLN-012	Pigment changeover cleanup	trapped colors, gaskets and joints	wrong shade / contamination
CLN-013	Preservative residue in QC sampling	neutralization during bioburden testing	false microbial negatives
CLN-014	Shared vessel cleaning between products	high-risk formula sequence and clearances	cross-product contamination
CLN-015	CIP recipe control	flow, temperature, concentration and time	incomplete internal cleaning
CLN-016	CIP conductivity verification	rinse endpoint and probe reliability	chemical cleaner carryover
CLN-017	CIP return line deadlegs	flow distribution and valve geometry	persistent reservoir of biofilm
CLN-018	Hose and transfer line sanitization	storage, drying and cap status	cross-lot microbial contamination
CLN-019	Filling nozzle cleaning	disassembly access and valve seats	residual product/microbes in nozzle
CLN-020	Tool cleaning and color segregation	dedicated implements and lockers	cross-shade or allergen transfer
CLN-021	Facility floors/drains sanitation	splash and backflow prevention	aerosol contamination of production
CLN-022	Handwashing station hygiene	soap/disinfectant and touch points	personnel introduce contamination
CLN-023	Environmental hygiene monitoring	risk locations and frequency	undetected environmental source
CLN-024	Cleaning visual inspection qualification	lighting, access and residual visibility	soils overlooked after cleaning
CLN-025	Equipment cleaning after maintenance	lubricant and metal debris removal	mechanical contaminants in batch
CLN-026	Housekeeping contractor supervision	SOP and approved cleaning supplies	uncontrolled products near line
CLN-027	Cleaning verification against residues	analytical methods and risk-based limits	unjustified cleaning acceptance
CLN-028	Disinfection of sampling devices	method compatibility and storage	cross contamination of test sample

06 | COMPUTER SYSTEMS / DATA INTEGRITY

21 distinct assessment topics • 63 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
IT-001	Electronic master recipe access	approved parameters and roles	unauthorized formula modification
IT-002	Batch execution system audit trail	original records and change timestamps	untraceable manufacturing deviations
IT-003	LIMS test result lifecycle	sample identity, data edits and approvals	unreliable QC release
IT-004	ERP raw material lot status	quarantine and expiry constraints	unreleased ingredient issued
IT-005	Weighing system barcode recipe	recipe version and verified match	wrong ingredients dispensed
IT-006	Warehouse inventory batch genealogy	inbound/outbound and FEFO	incomplete recall traceability
IT-007	Electronic label artwork release	controlled approval and version	wrong INCI or allergen label printed
IT-008	Supplier management database	approved lists and COA linkage	unqualified material purchased
IT-009	Calibration and maintenance CMMS	work orders and overdue flags	critical out-of-calibration equipment used
IT-010	SCADA water loop trending	sensor integrity and alarms	microbial water drift hidden
IT-011	Environmental sensor data retention	temperature and humidity integrity	degraded product stored without record
IT-012	Electronic signature authorization	identity and role restrictions	unapproved electronic batch release
IT-013	User account provisioning	joiner/mover/leaver and least privilege	unauthorized changes to records
IT-014	Audit trail periodic review	critical parameter change and exception	undetected deliberate/accidental edit
IT-015	Backup and disaster recovery testing	verified restore and continuity	batch and formula data lost
IT-016	System time synchronization	timestamps and sequence integrity	inability to reconstruct deviations
IT-017	Spreadsheet formula control	locked calculations and independent validation	incorrect yield or concentration result
IT-018	Cybersecurity ransomware resilience	access segregation and backups	unavailable quality records / production halt
IT-019	Data migration validation	records accuracy and units	misstated formulation or supplier specs
IT-020	Cloud service provider assurance	SLAs, ownership and exports	data access/retention failure
IT-021	AI-generated formulation outputs review	human approval and source validation	unsafe ingredient or wrong regulatory interpretation

07 | CONTRACT MANUFACTURING / PRIVATE LABEL

16 distinct assessment topics • 48 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
CMO-001	Private-label manufacturer due diligence	scope, license and ISO 22716 controls	unqualified contract manufacturer
CMO-002	Technical quality agreement definition	testing, release, retention and deviations	no accountable quality decision
CMO-003	Brand owner formula control	master formula and legal product identity	unauthorized formulation change
CMO-004	Private-label ingredient substitution	technical assessment and notification	unknown allergen or noncompliant ingredient
CMO-005	Contract packing line clearance	variant and print component control	wrong brand or batch on retail unit
CMO-006	Third-party laboratory testing	method transfer and reliable results	false accepted batch
CMO-007	CMO batch certificate release	actual manufacturing records and testing	unsupported finished good disposition
CMO-008	CMO deviation notifications	prompt quality event escalation	major contamination concealed
CMO-009	CMO CAPA implementation review	root cause and independent follow-up	recurring supplier defects
CMO-010	Supplier/CMO change control	site, process, package and formula changes	outdated safety assessment
CMO-011	Brand owner complaint data sharing	consumer safety signal and batch trace	unrecognized adverse event cluster
CMO-012	Responsible Person and brand duties	EU/UK/US market ownership	unreported consumer safety events
CMO-013	India cosmetic loan-license scope	permitted site and product categories	unauthorised loan-license production
CMO-014	Third-party warehouse oversight	stock rotation and storage constraints	degraded cosmetic distributed
CMO-015	Contract artwork approval workflow	mutual sign-off and claim review	illegal/deceptive labeling
CMO-016	CMO product recall coordination	traceability and action deadline	slow recall of unsafe product

08 | CREAMS / LOTIONS / EMULSIONS

22 distinct assessment topics • 66 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
EMUL-001	Oil phase heating	melt endpoint and thermal degradation	texture and odor defects
EMUL-002	Water phase heating	temperature and microbial reduction limits	phase instability or contamination
EMUL-003	Emulsifier predispersion	order and complete solubilization	coarse or unstable emulsion
EMUL-004	Oil-to-water addition rate	phase volume and mixing energy	inverted or broken emulsion
EMUL-005	Water-to-oil addition rate	emulsion type and stabilization	unexpected continuous phase behavior
EMUL-006	Vacuum level during emulsification	entrained air removal and boiling point	foam or oxidation
EMUL-007	High-shear homogenization pass	droplet size and temperature	unstable droplet distribution
EMUL-008	Shear-sensitive polymer addition	mixing sequence and viscosity	polymer breakage and poor texture
EMUL-009	Cooling curve management	wax crystallization and phase stability	graininess or viscosity drift
EMUL-010	Heat-sensitive actives addition	temperature and contact time	ingredient degradation
EMUL-011	Perfume addition below cutoff	volatile evaporation and heating	odor loss or allergen ratio drift
EMUL-012	Preservative addition sequence	solubility and homogeneous distribution	low local preservation
EMUL-013	Cream pH adjustment	mixing and acid/base over-addition	irritation or poor preservation
EMUL-014	Emulsion droplet-size monitoring	size distribution and stability trend	coalescence not detected
EMUL-015	Cream bulk hold time	time and microbiological protection	growth of objectionable organisms
EMUL-016	Air entrapment in cream	vacuum and filling settings	voids and oxidation
EMUL-017	Vessel discharge heel control	mixing dead zone and residual quantity	nonuniform last fill
EMUL-018	Hot filling of cream jars	temperature and closure performance	pack deformation or condensation
EMUL-019	Cold filling of cream tubes	fill viscosity and dosing	incorrect net content
EMUL-020	Lamellar structure stability	wax and shear regime	weeping and phase separation
EMUL-021	W/O emulsion preservative partition	water phase availability	underprotected internal phase
EMUL-022	Cream viscosity release	measurement geometry and temperature	out-of-range texture accepted

09 | DISTRIBUTION / LOGISTICS / SALES

18 distinct assessment topics • 54 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
DIST-001	Finished goods dispatch authorization	QA release and lot status	unreleased cosmetic sold
DIST-002	Pallet stacking and shrink wrapping	compression and physical protection	crushed/ruptured retail packs
DIST-003	Finished product temperature exposure	heat, frost and stability design	emulsion separation and degradation
DIST-004	Transport route qualification	summer temperatures and transit time	expired stability envelope
DIST-005	Cosmetic aerosol dangerous goods shipment	correct UN packaging and hazard label	accident during transport
DIST-006	Alcohol perfume transport documentation	flammable goods and local rules	unsafe carriage / regulatory seizure
DIST-007	E-commerce direct-to-consumer packing	breakage and leakage prevention	consumer damaged product
DIST-008	Distributor lot-level traceability	invoice and batch number mapping	ineffective market recall
DIST-009	Retail shelf storage guidance	sunlight and temperature	degraded product presented to consumer
DIST-010	Product shelf-life rotation FEFO	expiry across warehouse and retailers	expired cosmetic sold
DIST-011	Returns and reverse logistics	tampering, use history and segregation	used stock returned to market
DIST-012	Counterfeit and product diversion surveillance	authenticity and chain of custody	unsafe counterfeit products sold
DIST-013	Product sample giveaway controls	batch and labeling traceability	untraceable adverse event source
DIST-014	Export documentation and customs	permitted ingredients and market paperwork	border seizure/noncompliance
DIST-015	Transit leakage investigation	closure defect and lot patterns	widespread defective packaging missed
DIST-016	Distribution recall rehearsal	consumer notifications and recovery efficiency	affected lots remain in use
DIST-017	Third-party logistics contract audit	environment, inventory and trace	uncontrolled external supply chain
DIST-018	Online claims advertisement review	approved, substantiated marketing	misleading consumer claims

10 | EHS / OCCUPATIONAL SAFETY / ENVIRONMENT

29 distinct assessment topics • 87 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
EHS-001	Combustible powder dust risk	particle and ignition source evaluation	dust fire/explosion and injury
EHS-002	Ethanol storage and transfer	flash point and static grounding	flash fire or explosion
EHS-003	Aerosol LPG propellant handling	leak control and ventilation	flammable vapor ignition
EHS-004	Organic solvent mixing	LEL detection and ATEX-style hardware where required	fire / harmful vapor exposure
EHS-005	Caustic soap manufacturing	corrosive charging and PPE	chemical burns
EHS-006	Oxidative hair dye raw materials	sensitizer controls and closed handling	occupational dermatitis
EHS-007	Hair bleach persulfate handling	aerosolized allergenic powder	occupational asthma
EHS-008	Fragrance sensitizer occupational exposure	closed transfers and gloves	allergic contact dermatitis
EHS-009	Isocyanate or reactive adhesive exclusion	ingredient and chemical review	unexpected respiratory sensitization
EHS-010	Nail polish solvent exposure	local exhaust ventilation and limits	neurotoxic or fire hazard
EHS-011	Compressed gas cylinder storage	secure racking and valve protection	gas leak / impact injury
EHS-012	Confined space in large tanks	entry permit, oxygen and rescue	asphyxiation or injury
EHS-013	Machine guarding on mixers	interlock and start prevention	entanglement or crushing
EHS-014	Lockout tagout of electrical equipment	energy isolation and testing	unexpected energization injury
EHS-015	Hot surface and steam lines	thermal insulation and warnings	burn injuries
EHS-016	Workplace noise from mills/compressors	measurement and hearing protection	noise-induced injury
EHS-017	Manual handling of drums	lifting design and training	musculoskeletal injury
EHS-018	Forklift and pedestrian traffic	barriers, training and routes	collision injuries
EHS-019	Chemical storage incompatibility	acid/alkali, oxidizers, flammables	hazardous reaction / release
EHS-020	SDS availability and chemical labeling	accurate GHS classification	improper first aid or handling
EHS-021	Eyewash and safety shower readiness	access and flow performance	worsened chemical exposure outcome
EHS-022	Spill response equipment	kits, containment and drills	worker exposure / uncontrolled runoff
EHS-023	Waste solvent management	flammable waste and licensed disposal	fire and environmental violation
EHS-024	Wastewater COD and surfactants	effluent treatment and discharge compliance	polluting discharge
EHS-025	Plastic packaging waste compliance	EPR and waste segregation as applicable	legal/environmental noncompliance
EHS-026	Air emission/VOC compliance	exhaust capture and permitting	worker/neighborhood exposure
EHS-027	Fire extinguishing and evacuation drills	hazard response and coverage	delayed emergency response
EHS-028	Occupational exposure monitoring	risk-based sampling and records	invisible chronic exposure unaddressed
EHS-029	EHS event linkage to QA	product/area cross-impact and restart	batch contaminated after incident

11 | ENGINEERING / MAINTENANCE / UTILITIES

30 distinct assessment topics • 90 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
ENG-001	Site utilities risk-based maintenance	critical service priority and backup	production loses essential controls
ENG-002	Boiler and steam system	steam quality and condensate control	thermal process deviation
ENG-003	Process hot water supply	set point and recirculation	incomplete material melting
ENG-004	Chilled water system	temperature, microbiological and pressure control	cooling failure or leakage
ENG-005	Compressed air compressors	oil-free quality and maintenance	oil contamination enters process
ENG-006	Compressed air filtration and dryer	dew point, oil mist and filter performance	compressed air deposits contaminants
ENG-007	Vacuum generation system	pressure stability and backflow prevention	process quality disruption
ENG-008	Nitrogen blanket supply	purity and pressure	oxidation or oxygen deficiency hazard
ENG-009	Air handling unit operation	air filters and pressure cascades	dust and microbial contamination
ENG-010	HVAC humidity controls	RH alarm and product exposure	powder clumping or microbial growth
ENG-011	HVAC filter differential pressure	change schedule and bypass	unfiltered air reaches production
ENG-012	Building envelope and finishes	cracks, leaks and cleanability	microbial and pest ingress
ENG-013	Doors, personnel/material flows	segregation and open-door control	cross contamination
ENG-014	Drain design and trap integrity	backflow and standing water	microbial reservoir near process
ENG-015	Lighting protection over exposed product	glass fragments and lux	physical contamination
ENG-016	CIP water pressure / flow	cleaning hydraulic coverage	soil retained in lines
ENG-017	Product-contact pumps maintenance	seals, gaskets and lubricants	foreign matter introduced
ENG-018	Lubricants and food/cosmetic-grade contact	approved grade and leak barriers	chemical contamination
ENG-019	Equipment surface corrosion inspection	rouging, metal shedding and finish	particles or bioburden harborage
ENG-020	Conveyor maintenance	belt wear and cleaning	foreign particles in packaging
ENG-021	Electrical supply interruptions	UPS critical controls and alarm tests	loss of validated batch parameters
ENG-022	Backup generator readiness	start tests and fuel condition	failure to protect critical storage
ENG-023	Electrical earthing and bonding	continuity and static discharge	fire in solvent areas
ENG-024	Flammable area classification	zone assessment and Ex-rated hardware	ignition during alcohol use
ENG-025	Tank load cells qualification	drift and measurement validation	wrong ingredient quantity
ENG-026	Weighbridge and transfer scales	calibration and traceability	incorrect bulk mass tracking
ENG-027	Engineering change management	process impact and QA sign-off	unvalidated equipment changes
ENG-028	Spare parts verification	gasket/elastomer equivalent grade	migration, leaks or product contact issue
ENG-029	Equipment breakdown product containment	open lines and hygienic return to service	batch exposed during repair
ENG-030	Facility pest proofing	building entry points and inspections	pest contamination of ingredients

12 | EYE COSMETICS / MASCARA / EYELINER

18 distinct assessment topics • 54 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
EYE-001	Mascara wax melting and emulsification	melting profile and mixing	clumping in eye cosmetic
EYE-002	Mascara preservative challenge	eye-region product safety and repeated use	contamination-linked eye infection
EYE-003	Mascara pigment identity	eye-area permitted colorants	ocular irritation from illegal dye
EYE-004	Mascara rheology and brush pickup	viscosity and applicator design	injury from clumps and poor deposition
EYE-005	Mascara bottle neck wiper fit	air ingress and excess loading	microbial ingress or unsafe dose
EYE-006	Mascara brush/rod cleanliness	assembly and foreign particles	ocular injury / contaminated applicator
EYE-007	Liquid eyeliner filling	bioburden and tip/brush compatibility	eye infection / leakage
EYE-008	Eyeliner pencil extrusion	wax matrix and pigment dispersion	frangible core and eye injury
EYE-009	Eyeliner pencil sharpener compatibility	wood debris and core quality	mechanical eye irritation
EYE-010	Powder eye shadow colorant compliance	eye-specific approved pigment	illegal colorant adjacent to eye
EYE-011	Eye shadow pan pressing	pan adhesion and dusting	powder fallout into eye
EYE-012	Eye-area product preservative-free claims	low-risk justification and in-use challenge	underestimated microbial risk
EYE-013	Eye makeup packaging seal	closure and contamination ingress	spoilage during storage
EYE-014	Eye cosmetic complaint escalation	reported infection and serious reaction	consumer harm not detected
EYE-015	Contact lens user warning review	foreseeable exposure and label advice	increased ocular irritation
EYE-016	Sensitive-eye product formulation	allergens and irritation profile	sensitization in users
EYE-017	Eyelash glue product boundary	adhesive/medical device versus cosmetic status	wrong legal and safety framework
EYE-018	Eyelash / brow serum claim review	cosmetic vs drug claims and prostaglandin analogs	unlawful / unsafe eye-area product

13 | FACILITY DESIGN / HVAC / HYGIENE ZONING

20 distinct assessment topics • 60 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
FAC-001	Personnel flow and material zoning	one-way moves and clean-to-dirty traffic	cross-product contamination
FAC-002	Adjacent fragrance and neutral product areas	odor migration and segregation	unwanted fragrance in unscented lines
FAC-003	Pigment and white cream segregation	colored particle control	shading contamination
FAC-004	Powder and liquid manufacturing zoning	dust and spill isolation	powder contamination of liquids
FAC-005	Airflow from dirty to exposed product	pressure cascade as justified	microbes or dust reach open batch
FAC-006	Air treatment filter replacement	leaks and change intervals	uncontrolled airborne contaminants
FAC-007	Humidity management in dry cosmetics	dewpoint and RH stability	clumping or microbial risk
FAC-008	Temperature comfort vs stability	plant operating range and exposure	bulk product viscosity drift
FAC-009	Cleanable wall-floor covings	crack, joint and cleaning access	biofilm/pest harborages
FAC-010	Floor drains and backflow	drain traps and splash separation	drain organism spread
FAC-011	Handwash facilities at hygiene entry	distance and supplies	staff fail hygienic preparation
FAC-012	Hair/beard containment gowning stations	controlled change and PPE storage	personnel hair contamination
FAC-013	Pest-proof external doors and windows	seals and proofing audit	insect/rodent ingress
FAC-014	Solvent room ventilation design	capture, LEL and hazard classification	flammable mixture accumulates
FAC-015	Raw material sampling area engineering	containment and cleaning flow	raw cross-contamination
FAC-016	Central cleaning equipment storage	clean/dirty tool separation	contaminated tools introduced
FAC-017	Rework material handling route	status and protected handling	unapproved material crosses line
FAC-018	Finished product exit route	dirty-to-clean boundaries	finished packs exposed to chemicals
FAC-019	Facility water ingress and condensation	roof leaks and dewpoints	microbial contamination and wet stock
FAC-020	Facility expansion impact assessment	utilities, zoning and qualification	previously approved control invalid

14 | FRAGRANCE / FLAVOR / COLOR COMPLIANCE

18 distinct assessment topics • 54 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
FRAG-001	Fragrance allergen threshold calculation	leave-on/rinse-off category and concentration	underdeclared sensitizer
FRAG-002	Fragrance composition change notice	new allergens and restricted ingredients	obsolete INCI/allergen statement
FRAG-003	IFRA conformity certificate review	correct IFRA category and amendment	unsafe fragrance loading
FRAG-004	Natural fragrance constituent variability	season and natural marker concentrations	unreliable allergy assessment
FRAG-005	Phototoxic essential oil screening	furocoumarins and intended exposure	phototoxic reaction
FRAG-006	Fragrance oxidation products	limonene/linalool oxidation controls	sensitization risk increases in shelf life
FRAG-007	Fragrance batch traceability	composition code and vendor revision	incorrect perfume used
FRAG-008	Odor/taint migration from packaging	permeation and volatile interactions	off-odor and potential compatibility issue
FRAG-009	Solvent choice in fragrance premix	flash point and toxicological grade	flammability or impurity exposure
FRAG-010	Colorant permission by market	CI number and annex entries	illegal pigment formula
FRAG-011	Color additive purity	heavy metals and restricted intermediates	systemic contamination risk
FRAG-012	Color stability against pH/light	shade integrity under use	visible quality complaint and claim issue
FRAG-013	Peroxide in fragrance oils	oxidative degradation markers	sensitizing oxidized constituents
FRAG-014	Fragrance dosing skid accuracy	mass flow and premix homogeneity	allergen concentration error
FRAG-015	Allergen labeling artwork sign-off	INCI declaration matching formula	consumer exposure without warning
FRAG-016	Colorant cross-contamination	dark/light pigment shared equipment	wrong shade or undeclared colorant
FRAG-017	Flavor in toothpaste/lip products	oral exposure and label compliance	irritation or unintended ingestion
FRAG-018	Fragrance retention sample conditions	volatility and oxidation of retain	unreliable complaint comparisons

15 | HAIR COLOR / BLEACH / STRAIGHTENERS

26 distinct assessment topics • 78 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
HAIR-001	Oxidative hair dye precursor receipt	restricted precursors and purity	sensitizer above allowed concentration
HAIR-002	Hair dye developer peroxide content	assay and stability	chemical burn or nonperforming developer
HAIR-003	Two-part dye kit ratio control	colorant to developer mix	excess reactive exposure
HAIR-004	Hair dye precursor premixing	homogeneity and operator exposure	sensitizer pockets or skin injury
HAIR-005	Hair dye color stability	oxidation during hold	unexpected shade and irritancy
HAIR-006	Hair dye patch-test warning artwork	appropriate consumer directions	allergy risk warning omitted
HAIR-007	Hair dye salon professional-use labeling	worker PPE and use restrictions	occupational or consumer exposure
HAIR-008	Bleach persulfate powder handling	inhalable dust and contamination	respiratory sensitization
HAIR-009	Bleach developer pack compatibility	oxygen evolution and cap vent	bottle rupture or leakage
HAIR-010	Hair bleach mixing heat	exotherm and mixture ratio	scalp/skin burns
HAIR-011	Hair straightening reducing agent concentration	thioglycolate/pH and market limits	hair and skin damage
HAIR-012	Relaxer alkaline content	caustic alkali and pH	chemical burns
HAIR-013	Formaldehyde-releasing straightener review	heating, emission and prohibited ingredients	inhalation hazard and regulatory violation
HAIR-014	Heat-activated hair product fumes	worker and consumer breathing zone	irritating/toxic vapor exposure
HAIR-015	Hair conditioning emulsion mixing	emulsifier and cooling profile	phase instability
HAIR-016	Hair serum silicone blend	compatibility and shear	phase splitting or overdose
HAIR-017	Hair oil botanical extract identity	authenticity and oxidation	irritation or rancidity
HAIR-018	Hair color strand test method	representative shade and development	misleading product claims
HAIR-019	Hair dye pack kit reconciliation	matching developer/colorant instructions	wrong mixture used
HAIR-020	Hair color development time labeling	exposure duration and warnings	long exposure causes irritation
HAIR-021	Hair spray solvent blend	flash point and propellant compatibility	flammability or can failure
HAIR-022	Hair styling gel preservative challenge	consumer finger contact and use life	microbial spoilage
HAIR-023	Scalp treatment classification	anti-dandruff, hair-growth medicinal claims	wrong product regulatory pathway
HAIR-024	Hair dye professional distribution control	market-specific warnings and languages	untrained use without instructions
HAIR-025	Hair powder root touch-up dust	particle deposition and inhalation	respiratory exposure
HAIR-026	Hair mask jar microbial control	large opening and repeated wet exposure	in-use microbial contamination

16 | HERBAL / NATURAL / ORGANIC COSMETICS

16 distinct assessment topics • 48 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
BOT-001	Botanical species authentication	taxonomic identity and reference material	wrong plant or toxic substitution
BOT-002	Plant part and geographic source	standardized harvested organ	inconsistent bioactive/allergen profile
BOT-003	Botanical extraction solvent	residuals and grade	unsafe solvent remains in cosmetic
BOT-004	Extract concentration adjustment	marker assay and solids	variable potency / color shift
BOT-005	Botanical pesticide residues	source contamination and testing	toxic residue exposure
BOT-006	Botanical heavy metal impurities	soil source and elemental screening	contaminated botanical ingredient
BOT-007	Botanical microbiological contamination	drying, storage and processing hygiene	spore/pathogen enters batch
BOT-008	Aflatoxin/mycotoxin source assessment	stored plant substrate and testing	harmful secondary metabolite exposure
BOT-009	Phototoxic botanical furocoumarins	expressed citrus extracts and use levels	photo-induced skin injury
BOT-010	Botanical natural allergen content	seasonal variability and EU label mapping	unreported sensitizer exposure
BOT-011	Essential oil oxidation control	air and light exposure	irritant oxidation compounds increase
BOT-012	Organic/natural claim definition	ISO 16128 and scheme-specific evidence	misleading marketing claim
BOT-013	Organic certification chain of custody	certification scope and lot traceability	unsubstantiated organic claim
BOT-014	Plant-based preservative validation	challenge efficacy and formula matrix	microbial spoilage under unsupported 'natural' claim
BOT-015	Botanical extract discoloration stability	polyphenol oxidation and pH	visual failure during storage
BOT-016	Botanical supply sustainability/trace	wild harvest and authenticity	unreliable origin and adulteration

17 | HUMAN RESOURCES / TRAINING / ADMINISTRATION

17 distinct assessment topics • 51 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
HR-001	Job descriptions and competence profiles	roles and supervision responsibility	untrained personnel perform critical step
HR-002	GMP / ISO 22716 induction program	training before independent work	poor hygiene and process noncompliance
HR-003	Production operator practical qualification	weighing, cleaning and dispensing skills	ingredient error or contamination
HR-004	QC analyst method training	method execution and data review	invalid lab results
HR-005	Microbiology analyst qualification	neutralization and aseptic sampling competence	microbial false negative
HR-006	Equipment maintenance technician training	hygienic reassembly and line release	post-maintenance contamination
HR-007	Hygiene and gowning training	handwash, hair/beard cover and behavior	personnel-borne contamination
HR-008	Personal health and illness reporting	wounds, infections and access restrictions	staff-introduced microbial source
HR-009	Jewelry and personal item policy	foreign object and hygiene control	physical particles in bulk
HR-010	Contractor GMP access training	escorted areas and hygiene	uncontrolled contractor contamination
HR-011	Shift handover communication	open deviations and batch status	critical event not escalated
HR-012	Fatigue and staffing review	workload and peak demand	dispensing or labeling errors
HR-013	Training effectiveness evaluation	observed competency and retraining	ineffective training accepted
HR-014	Visitor management and escort	controlled production access	unauthorized exposure to product
HR-015	Training record completeness	date, version and demonstrated skill	no proof of operator qualification
HR-016	Administrative archive security	record integrity and retrieval	loss of release/complaint evidence
HR-017	Cleaning personnel chemical awareness	SDS and dilution competence	chemical injury or inadequate cleaning

18 | INNOVATION / PRODUCT TRANSFER / LAUNCH

14 distinct assessment topics • 42 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
NEW-001	Technology transfer document package	formula, critical parameters and approved ranges	receiving plant cannot reproduce quality
NEW-002	Pilot to commercial batch comparison	shear, heat transfer and mixing scale	unexpected physical instability
NEW-003	First commercial batch heightened review	in-process samples and QA oversight	launch batch risks not identified
NEW-004	New equipment product-contact assessment	cleanability and compatibility	new contaminants at scale
NEW-005	New primary pack launch approval	compatibility, sealing and migration	unnoticed retail pack failure
NEW-006	New market launch regulatory gate	notification/registration and label approval	unlawful product placement
NEW-007	Promotional sample launch control	retention and label requirements	untraceable adverse reaction
NEW-008	New fragrance variant evaluation	ingredient and allergen dossier update	obsolete safety/label decisions
NEW-009	New color/shade variant evaluation	pigment legality and batch shade	unapproved variant marketed
NEW-010	Discontinued material replacement	technical equivalence and PET impact	altered preservation or stability
NEW-011	Production campaign sequencing	cleaning and allergen/color crossover	carryover into launch batch
NEW-012	First stability commitment at launch	protocol and scientific shelf life	unsubstantiated expiry period
NEW-013	Scale-up supplier synchronization	component specs and lot quality	incompatible new ingredient or pack
NEW-014	Early complaint monitoring after launch	high-signal trend thresholds	emerging hazard missed

19 | MAKEUP / FOUNDATION / LIP COSMETICS

20 distinct assessment topics • 60 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
MAKE-001	Foundation pigment dispersion	wetting and particle distribution	uneven shade or color streaks
MAKE-002	Foundation emulsion phase control	water/oil ratio and coalescence	instability and microbial risk
MAKE-003	Foundation shade master approval	lighting, delta E and reference sample	wrong shade shipped
MAKE-004	Foundation preservative compatibility	pigment adsorption and efficacy	product spoilage during use
MAKE-005	Concealer wax melting	temperature and crystal formation	graininess or phase split
MAKE-006	BB/CC cream active claim review	sunscreen or therapeutic claim classification	unlawful claim on multiuse product
MAKE-007	Lipstick wax/oil melting	temperature and volatile loss	grainy stick or odor defect
MAKE-008	Lipstick pigment grinding	dispersion and abrasive particle	lip injury or uneven color
MAKE-009	Lipstick mold filling	cooling gradient and voids	stick cracking or hidden void
MAKE-010	Lipstick demolding and flaming	surface quality and heat exposure	melting/geometry failure
MAKE-011	Lip balm oral incidental exposure	lip contact and ingredient limits	toxicity from repeated ingestion
MAKE-012	Lip gloss applicator return path	microbial contamination from brush	in-use product contamination
MAKE-013	Lip tint colorant evaluation	authorized cosmetic dyes and staining	illegal dye or sensitization
MAKE-014	Blusher pressed powder compacting	pressure and binder control	powder breakage or contamination
MAKE-015	Loose powder sieving	mesh and metal detection	foreign particle injury
MAKE-016	Loose powder inhalation profile	particle size and dust	respiratory exposure
MAKE-017	Highlighter shimmer material	particle purity and heavy metal	contaminant / skin irritation
MAKE-018	Makeup shade line clearance	previous color campaign residue	mixed shade or undeclared colorant
MAKE-019	Makeup batch reference sample	controlled lighting and retention	false shade comparisons
MAKE-020	Makeup preservation in multiuse pots	repeated finger contamination	microbial spoilage during consumer use

20 | MICROBIOLOGY / PRESERVATION EFFICACY

30 distinct assessment topics • 90 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
MIC-001	Microbiological risk category assignment	ISO 29621 suitability and intended users	incorrect microbiological low-risk exemption
MIC-002	Finished-product microbial limits	ISO 17516 and market specifications	contaminated cosmetic accepted
MIC-003	Baby eye and mucosal product limits	higher-risk user group and tests	eye infection or infant exposure
MIC-004	Objectionable organism testing	specified bacteria/yeast control	hazardous microbe passes release
MIC-005	Pseudomonas aeruginosa identification	selective method and confirmation	eye/skin pathogen undetected
MIC-006	Staphylococcus aureus identification	selective media and confirmation	skin pathogen undetected
MIC-007	Candida albicans identification	yeast confirmation and enrichment	yeast contamination unrecognized
MIC-008	Escherichia coli identification	method suitability and controls	fecal contamination not detected
MIC-009	Total aerobic microbial count	dilution, recovery and incubation	false low contamination counts
MIC-010	Yeast and mold enumeration	medium and incubation validity	fungal spoilage risk overlooked
MIC-011	Neutralizer efficacy study	preservative interference and spike recovery	false negative micro results
MIC-012	Growth promotion test of media	challenge organisms and acceptance	microbial method lacks detection
MIC-013	Positive / negative control program	contamination monitoring and strain traceability	unreliable laboratory outcomes
MIC-014	Environmental surface monitoring	site risk plan and trend evaluation	persistent plant bioburden missed
MIC-015	Water microbiology monitoring	source and point-of-use sampling	water-borne contamination missed
MIC-016	Preservation efficacy test (PET)	ISO 11930 inoculum and acceptance	ineffective product preservation accepted
MIC-017	PET reference organism preparation	viability, count and culture trace	invalid challenge test
MIC-018	PET challenge dose and mixing	inoculum uniformity and sampling	invalid kill/recovery conclusions
MIC-019	PET sampling time intervals	timing and method recovery	incorrect preserved-status conclusion
MIC-020	PET method matrix suitability	surfactant or hydrophobic interference	false microbial reduction
MIC-021	In-use contamination study	opening/dispensing simulation and storage	consumer use growth underestimated
MIC-022	Manufacturing biofilm surveillance	organism recurrence and sanitation	persistent water-line contamination
MIC-023	Microbial isolate identification and trending	species and source linkage	recurring pathogen source unresolved
MIC-024	Microbiological out-of-specification review	lab error versus true batch contamination	unsafe lot released
MIC-025	Micro sample holding time	transport temp and analysis time	microbial counts change before test
MIC-026	Controlled inoculum culture storage	strain identity and contamination	invalid challenge test
MIC-027	Preservative content-vs-PET correlation	dose and compatibility	false confidence from chemical assay
MIC-028	Micro lab biosafety and waste handling	strain-specific exposure and decontamination	worker biological exposure
MIC-029	Clean bench / BSC suitability	containment or product cleanliness needs	spread contamination across samples
MIC-030	Microbiological retesting policy	scientific rationale and confirmed deviation	test-into-compliance release

21 | NAIL POLISH / REMOVERS / NAIL PRODUCTS

16 distinct assessment topics • 48 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
NAIL-001	Nail lacquer solvent blend	acetate/alcohol solvent purity and flashpoint	unsafe vapor or viscosity shift
NAIL-002	Nitrocellulose receipt and wetting	water/alcohol content and ignition controls	flammable solid fire
NAIL-003	Nail lacquer resin dissolution	solubility and temperature	film defects or sediment
NAIL-004	Plasticizer concentration	permitted ingredient and flexibility	brittle film or toxic exposure
NAIL-005	Nail color pigment grinding	size, dispersion and metal impurities	surface defect and contamination
NAIL-006	Nail lacquer rheology	shear and bottle brush consistency	poor application or sediment
NAIL-007	Nail lacquer glass bottle filling	vapor control and accurate volume	flammable vapor accumulation
NAIL-008	Nail polish brush assembly	bristle shedding and cap closure	foreign bodies or evaporation
NAIL-009	Nail polish cap torque	seal and solvent evaporation	thickened or leaking product
NAIL-010	Nail remover solvent purity	acetone/ethyl acetate and contaminants	skin irritation or flammability
NAIL-011	Nail remover wipes packaging	solvent vapor barrier	dry wipes and unexpected concentration
NAIL-012	UV/LED cured nail gel composition	sensitizing methacrylates and photo-initiators	contact sensitization
NAIL-013	Nail gel lamp compatibility claim	cure dose and skin exposure	incomplete curing/contact allergen
NAIL-014	Nail polish label warnings	flammability and exposure precautions	consumer injury
NAIL-015	Artificial nail adhesive classification	product category and cyanoacrylate exposure	adhesive injury or regulatory mismatch
NAIL-016	Nail cosmetic solvent VOC management	ventilation and emission limit	worker/air pollution exposure

22 | PACKAGING / LABELING / FILLING

31 distinct assessment topics • 93 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
PACK-001	Plastic bottle resin qualification	polymer identity and migration	unsafe extractables or deforming pack
PACK-002	Glass bottle/vial quality	chipping, cleanliness and fracture	consumer cuts or particles
PACK-003	Tube laminate compatibility	barrier and solvent interaction	leak or product degradation
PACK-004	Aluminum tube interior lacquer	coating continuity	metal contamination or corrosion
PACK-005	Jar liner and seal	food/cosmetic contact suitability	chemical migration or leakage
PACK-006	Airless pump and piston	seal, dispensing and in-use contamination	contamination or poor dose
PACK-007	Dropper pipette/elastic bulb	rubber compatibility and extractables	leachable contaminants in serum
PACK-008	Spray nozzle and actuator	droplet distribution and clogging	consumer inhalation/poor use
PACK-009	Roll-on ball and insert	fit, return flow and hygiene	in-use back contamination
PACK-010	Bottle neck finish control	closure interface dimensions	leaks during storage
PACK-011	Cap torque control	torque and capping head performance	leakage or consumer access problem
PACK-012	Induction seal process	liner identity and heat dwell	missing or weak tamper seal
PACK-013	Heat sealing of sachet/pouch	seal time and strength	microbial ingress or moisture loss
PACK-014	Tube crimping/sealing	alignment and jaw temperature	cream leakage
PACK-015	Automatic volumetric filling	calibration and viscosity variation	incorrect net content
PACK-016	Piston filler seal wear	particle shedding and air ingress	visible contamination
PACK-017	Mass/weight filling control	tare and measurement error	underfilled cosmetic pack
PACK-018	Inline checkweigher	challenge checks and reject function	incorrect net content released
PACK-019	Bulk filler cleaning and product changeover	cleanliness and first-off approval	cross-product contamination
PACK-020	Foil blister / unit-dose cosmetic	seal integrity and component compatibility	pack barrier failure
PACK-021	Label printer / coding head	batch, manufacture date, expiry	untraceable/expired product
PACK-022	Artwork and INCI order	ingredient declaration and current recipe	undeclared ingredients / allergens
PACK-023	Market language and warning artwork	translated mandatory statements	unsafe use or legal noncompliance
PACK-024	QR/2D code product link	traceable identity and correct link	wrong product information
PACK-025	Line clearance for packaging	old label and container elimination	wrong product/variant labeling
PACK-026	Batch coding ink compatibility	legibility and toxic migration	untraceable pack or ink contamination
PACK-027	Camera vision inspection	validated reject function and thresholds	misprinted or unlabeled product passes
PACK-028	Tamper-evidence band and shrink wrap	heat and application consistency	unnoticed tampering or product damage
PACK-029	Case packing and shipper ID	lot grouping and inventory reconciliation	recall traceability lost
PACK-030	Consumer closure opening force	human factors and intended users	spillage or child exposure
PACK-031	Primary pack CCIT/transport tests	as relevant to cosmetic barrier and leaks	loss of barrier or product protection

23 | PERFUME / BODY MIST / COLOGNE

20 distinct assessment topics • 60 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
PERF-001	Ethanol incoming identity	grade and adulterant impurities	toxic solvent substitution
PERF-002	Fragrance concentrate blending	allergen loading and traceable lots	excess allergen in finished perfume
PERF-003	Alcohol-water blending	concentration and volume contraction	wrong strength and odor profile
PERF-004	Perfume maceration time	solubility and fragrance maturation	haze or unstable olfactory character
PERF-005	Cold chilling / haze removal	temperature and filtration criteria	precipitation in retail bottle
PERF-006	Perfume final filtration	filter compatibility and integrity	particles or fragrance adsorption
PERF-007	Perfume color addition	authorized dyes and stability	staining or illegal colorant
PERF-008	Perfume headspace management	oxygen and volatile preservation	oxidation or evaporation
PERF-009	Explosion-proof blending equipment	classification and grounding	flammable ignition event
PERF-010	VOC control in perfume filling	ventilation and emissions	worker exposure / environmental exceedance
PERF-011	Perfume glass flacon compatibility	glass coating and stress resistance	leakage or breakage
PERF-012	Spray pump/crimp integrity	seal force and spray volume	leak, failure or unintended exposure
PERF-013	Perfume crimping machine settings	crimp diameter and sealing	evaporation and leakage
PERF-014	Perfume vapor leak detection	equipment seals and work area	flammable vapor accumulation
PERF-015	Perfume batch odor comparison	retained reference and panel conditions	wrong or off-odor product release
PERF-016	High-strength fragrance allergen label	leave-on threshold and variants	undeclared sensitizer
PERF-017	Body mist container corrosion	hydroalcoholic compatibility	metal contamination / leakage
PERF-018	Consumer spray inhalation review	droplet size and foreseeable use	respiratory irritation
PERF-019	Perfume transporter flammable goods	UN classification and packing	unsafe dangerous goods shipment
PERF-020	Perfume alcohol mass balance	loss and spill reconciliation	uncontrolled product concentration

24 | POST-MARKET / COSMETOVIGILANCE

22 distinct assessment topics • 66 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
POST-001	Cosmetic complaint intake and classification	consumer report completeness and urgency	serious safety event delayed
POST-002	Serious undesirable effect reporting EU	competent authority, product and case specifics	reportable harm not escalated
POST-003	MoCRA serious adverse event reporting	US responsible person and records	FDA reportable event missed
POST-004	UK serious undesirable effect reporting	GB OPSS reporting obligations	serious harm not communicated
POST-005	Consumer allergic reaction investigation	ingredient, batch and medical timing	sensitizing product continues sale
POST-006	Consumer eye infection investigation	microbial lot testing and handling	contaminated eye product risk unrecognized
POST-007	Consumer chemical burn investigation	pH, active content and use instructions	unsafe product remains marketed
POST-008	Packaging leakage trend	transport/customer lot correlation	systemic pack defect missed
POST-009	Product color/odor complaint tracking	stability and oxidation	quality deterioration not investigated
POST-010	Microbial spoilage complaint tracking	organism isolation and retention	repeat contamination source overlooked
POST-011	Adverse event batch genealogy	lot and distribution reconciliation	affected batches not isolated
POST-012	Consumer patch-test misunderstanding	claim and leaflet instructions	inappropriate medical safety assurance
POST-013	False claims complaint response	marketing and evidence review	unsubstantiated claim persists
POST-014	Postmarket ingredient safety alert	authority and scientific intelligence	restricted ingredient not reformulated
POST-015	Recall decision authorization	risk severity and scope	unsafe lots remain with consumers
POST-016	Recall notification distribution channel	online stores, wholesalers and retailers	incomplete product withdrawal
POST-017	Recall effectiveness check	recovered units and reconciliations	unsafe products remain available
POST-018	Corrective re-labeling program	artwork and individual units tracking	undeclared allergens continue circulation
POST-019	Cosmetic product lifecycle retirement	stocks, expiry and market notifications	obsolete product remains listed
POST-020	Cosmetic packaging field correction	tamper, sealing and customer directions	repeated consumer exposure
POST-021	Regulatory agency communication records	correct facts and time-bound response	unsupported or late authority response
POST-022	Safety complaint signal trend	frequency, severity and lot/region	cluster of harm overlooked

25 | POWDERS / TALC / DRY COSMETICS

20 distinct assessment topics • 60 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
POWD-001	Talc receipt and asbestos-related testing	source certification and analytical controls	harmful fiber contamination
POWD-002	Kaolin / mica trace-metal screening	heavy metals and supplier controls	toxic impurity exposure
POWD-003	Dry pigment weigh-up	correct CI and grade	unapproved colorant present
POWD-004	Ribbon blending powder	time, speed and fill ratio	nonuniform powder ingredients
POWD-005	Vibro sifter mesh integrity	mesh size and foreign particle	oversized particle contamination
POWD-006	Powder pneumatic conveying	pipeline cleanliness and segregation	cross-product powder carryover
POWD-007	Air classification of fine powder	target particle-size distribution	inhalation hazard or poor performance
POWD-008	Powder blending humidity control	moisture and clumping	poor uniformity and shelf-life
POWD-009	Face powder binder spray	dose and distribution	compact breakage or inhomogeneity
POWD-010	Tablet/pan cosmetics pressing machine	force and dwell time	cracked pan and dust formation
POWD-011	Powder dust extraction	capture velocity and filter efficacy	operator inhalation or batch contamination
POWD-012	Powder segregation after blending	particle size / density mismatch	lot nonuniformity
POWD-013	Powder metal detector verification	detection sensitivity for metal	foreign particles released
POWD-014	Powder batch bulk sampling	top/middle/bottom homogeneity	failed blend accepted
POWD-015	Infant powder inhalation assessment	particle size and consumer use	respiratory injury in children
POWD-016	Aerosolized dry shampoo powder	aerosol propellant and inhalation	breathing-zone exposure
POWD-017	Loose pigment eye-area control	market-authorized use areas	ocular irritation or unlawful use
POWD-018	Powder packaging hopper hygiene	cleaning and moisture	spoilage or cross contamination
POWD-019	Dry blend hold-time qualification	humidity and exposure	microbial/appearance deterioration
POWD-020	Fine powder electrostatic risk	grounding and combustible dust properties	fire and dust explosion

26 | PROCUREMENT / SUPPLIER QUALITY

18 distinct assessment topics • 54 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
PUR-001	Raw ingredient supplier qualification	manufacturing source and grade	adulterated ingredient received
PUR-002	Preservative supplier qualification	validated grade and change notices	efficacy or toxicity shifts
PUR-003	Fragrance house assessment	allergen declaration and composition integrity	hidden restricted allergen
PUR-004	Pigment supplier assessment	CI grade and restricted metals	illegal/contaminated colorant
PUR-005	Packaging resin supplier approval	migration/compatibility dossier	unsafe pack contact component
PUR-006	Closure and pump supplier control	dosage and seal quality	leak or preservative exposure
PUR-007	Aerosol can supplier qualification	burst pressure and coating	rupture or corrosion
PUR-008	Outsourced QC laboratory qualification	method scope and competence	invalid product release evidence
PUR-009	Contract manufacturer qualification	ISO 22716 implementation and evidence	outsourced process contamination
PUR-010	Cleaning chemical purchasing	chemical identity and compatibility	toxic residues or damage
PUR-011	Calibration service purchasing	traceability and environmental fit	wrong measurement correction
PUR-012	Critical single-source supply continuity	alternative verification and lead time	uncontrolled substitute introduced
PUR-013	Ingredient change notification agreement	minimum notice and safety reassessment	unreviewed formulation drift
PUR-014	Vendor COA reliance assessment	identity verification and periodic testing	falsified or unfit COA accepted
PUR-015	Raw material authenticity surveillance	economically motivated adulteration	fraudulent unsafe ingredient
PUR-016	Price-driven material substitution	scientific approval and equivalence	lower-quality grade affects safety
PUR-017	Purchasing specification maintenance	approved latest technical specification	wrong material ordered
PUR-018	Supplier corrective action follow-up	evidence of recurrence prevention	repeated defective deliveries

27 | PRODUCT SAFETY / TOXICOLOGY

28 distinct assessment topics • 84 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
SAFE-001	Cosmetic ingredient toxicological profiles	NOAEL/POD, exposure and data quality	consumer systemic safety underestimated
SAFE-002	Margin of safety calculation	dose/exposure model and uncertainty	unsafe concentration accepted
SAFE-003	Skin sensitization assessment	fragrance and allergen potency	allergic contact dermatitis in users
SAFE-004	Skin irritation assessment	pH, surfactants, acids and duration	skin irritation or chemical burns
SAFE-005	Eye irritation assessment	ocular exposure of cleansers and eye cosmetics	ocular injury from foreseeable use
SAFE-006	Phototoxicity/photoallergy assessment	UV exposure and light reactive constituents	light-mediated skin damage
SAFE-007	Mutagenicity/genotoxicity review	ingredient hazards and impurities	genotoxic risk not considered
SAFE-008	Repeated dose toxicity review	chronic use and body exposure	long-term toxic effect overlooked
SAFE-009	Reproductive toxicity exposure	population and restricted ingredients	exposure-risk errors for vulnerable consumers
SAFE-010	Inhalation exposure assessment	spray size and breathing-zone use	respiratory irritation or inhalation harm
SAFE-011	Oral incidental exposure assessment	lip products and toothpaste ingestion	oral ingestion risk understated
SAFE-012	Infant and child exposure assessment	body weight and frequent application	inappropriate safety factor
SAFE-013	Damaged-skin exposure assessment	barrier disruption and penetration	increased systemic exposure
SAFE-014	Mucosal contact exposure assessment	lip, eye and oral category conditions	local tissue irritation overlooked
SAFE-015	Ingredient impurity profile review	heavy metals, solvents and process impurities	toxic contaminants reach product
SAFE-016	Nitrosamine and nitrosating-agent risk	amines, nitrite sources and storage	carcinogenic impurities may form
SAFE-017	1,4-Dioxane risk review	ethoxylated surfactants and analytical controls	unexpected trace impurity
SAFE-018	Formaldehyde release review	formaldehyde donor preservatives and pH	sensitization or regulatory exceedance
SAFE-019	Residual pesticide and botanical impurity	herbal ingredient sourcing and screening	contaminated natural extract used
SAFE-020	SCCS opinions applicability	latest ingredient use conditions	outdated toxicological evidence
SAFE-021	Nanomaterial dermal and inhalation safety	particle size and route of exposure	nano-specific hazard unassessed
SAFE-022	Unsafe consumer misuse assessment	foreseeable overuse and wrong application	inadequate label precaution
SAFE-023	Combined exposure from multi-product use	same ingredient from multiple daily products	aggregate dose underestimated
SAFE-024	Cosmetic pack migration safety	extractables, leachables and contact time	unsafe migrant exposure
SAFE-025	Undesirable effect causal review	medical seriousness and recurrence	severe harm not connected to product
SAFE-026	Product safety assessor independence	qualification and documented signed opinion	unsupported CPSR approval
SAFE-027	Preservation and microbiological safety link	challenge evidence and contamination risk	bacterial growth during normal consumer use
SAFE-028	Consumer-use testing protocol ethics	informed consent and stop rules	unmanaged test participant harm

28 | PRODUCTION / SHARED PROCESS EQUIPMENT

34 distinct assessment topics • 102 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
MFG-001	Weighing balance suitability	capacity, resolution and calibration	formula weighing error
MFG-002	Dispensing booth control	dust and ingredient carryover	cross-product contamination
MFG-003	Manual ingredient dispensing	independent identity and mass check	wrong raw material or dose
MFG-004	Barcode-guided formulation dispensing	recipe logic and override permissions	unapproved ingredient substitution
MFG-005	Premix vessel selection	material compatibility and cleaning	unintended carryover and corrosion
MFG-006	Vacuum emulsification vessel	vacuum integrity and mixing heat	entrained air and unstable emulsion
MFG-007	High-shear homogenizer	rotor-stator wear and shear control	metal particle or texture defect
MFG-008	Inline high-shear mixer	flow, speed and energy input	phase separation or inhomogeneity
MFG-009	Planetary mixer	scraper condition and dead zones	unmixed zones or particulate
MFG-010	Ribbon blender	powder mixing time and discharge	color/shade nonuniformity
MFG-011	Conical powder blender	fill ratio and blend validation	ingredient segregation
MFG-012	Screw feeder	feed rate and foreign material	incorrect transfer or contamination
MFG-013	Peristaltic transfer pump	tubing compatibility and fatigue	elastomer particulate or leakage
MFG-014	Lobe transfer pump	seal integrity and shear	microbial ingress or viscosity shift
MFG-015	Diaphragm pump	pulsation and diaphragm health	batch transfer variability
MFG-016	Colloid mill	gap setting and wear	oversize particles or metal debris
MFG-017	Triple roll mill	roll gap and guard controls	poor pigment dispersion
MFG-018	Bead mill	bead integrity and cleanout	solid debris in cosmetic bulk
MFG-019	Rotor/stator disperser	speed and thermal rise	unstable dispersed formulation
MFG-020	Heating jacket system	hot spots and temperature control	overheating or ingredient degradation
MFG-021	Cooling jacket system	controlled cooling ramp	crystallization or texture instability
MFG-022	Bulk recirculation loop	sanitation and minimum dead legs	biofilm or cross-batch carryover
MFG-023	Inline filter / strainer	mesh integrity and loading	foreign particles pass into bulk
MFG-024	Vessel manway access	closure and open time limits	airborne microbial contamination
MFG-025	Tank vent filter	integrity and breathing control	dust or microorganisms enter batch
MFG-026	Tank level sensor	calibration and overflow prevention	inaccurate addition or spillage
MFG-027	CIP spray ball coverage	contact and nozzle performance	unclean dead zones
MFG-028	Manual equipment cleaning	validated method and rinse coverage	residual detergent/previous product
MFG-029	Bulk transfer hose	sanitation and material compatibility	microbial ingress or extractables
MFG-030	Sampling valve / sampling tool	aseptic technique appropriate to cosmetics	unrepresentative or contaminated sample
MFG-031	Mixing cycle recording	time, speed and batch trend	unverified homogeneity
MFG-032	Mass reconciliation and yield	loss accounting and leak detection	material imbalance remains unresolved
MFG-033	Stainless-steel contact surface	finish, corrosion and weld integrity	metal particles or microbial harborage
MFG-034	Production area line clearance	prior labels, product and tools	wrong product mix and traceability loss

29 | QUALITY ASSURANCE / COSMETICS QMS

28 distinct assessment topics • 84 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
QA-001	Master manufacturing instruction approval	formula master and approved operating range	uncontrolled formula or process executed
QA-002	Master packaging instruction approval	artwork, codes and reconciliation	wrong packaging released
QA-003	Batch record issue and reconciliation	controlled copy and full traceability	loss of batch process evidence
QA-004	Batch record review	manufacturing exceptions and calculations	nonconforming batch released
QA-005	Finished product release authorization	identity, testing and deviation status	unsafe cosmetic distributed
QA-006	Deviations and nonconformance management	immediate containment and investigation	defect recurrence across lots
QA-007	CAPA root cause determination	scientific evidence and system action	repeated microbiological or mix-up failures
QA-008	CAPA effectiveness verification	recurrence and trend evidence	ineffective controls accepted
QA-009	Change control management	ingredient, packaging and claim changes	unassessed regulatory or safety impact
QA-010	Document lifecycle and revision control	current approved SOP distribution	obsolete instruction causes error
QA-011	Record retention and retrieval	lot records and market-period requirements	investigation unable to reconstruct manufacturing
QA-012	Out-of-specification investigations	confirmed lab results and batch impact	unsafe or falsely rejected lots
QA-013	Out-of-trend investigations	microbial counts and viscosity drift	incipient process deterioration missed
QA-014	Internal ISO 22716 audits	coverage and corrective actions	systemic manufacturing gaps persist
QA-015	Supplier audits and approval	ingredient quality and change notifications	unqualified raw materials introduced
QA-016	Management review agenda	safety complaints and quality KPIs	repeated quality signals not acted on
QA-017	Product quality review	complaint, OOS and stability trends	unrecognized repeat quality defects
QA-018	Process change evaluation	equivalence and cleaning impact	unexpected incompatibility or residuals
QA-019	Quality agreement controls	owner, tester and manufacturer responsibilities	release and reporting duties unclear
QA-020	Quarantine and rejection disposition	positive release and physical/electronic segregation	unapproved material used
QA-021	Rework and reprocessing approval	quality impact and documented criteria	microbial or stability defects hidden
QA-022	Returned finished goods assessment	tampering and storage history	unsafe return reintroduced into stock
QA-023	Product recall and mock recall	distribution genealogy and effectiveness	affected products remain with consumers
QA-024	Regulatory inspection readiness	authentic original records and site responses	inability to show cosmetic compliance
QA-025	Line clearance approval	previous product residues and artwork	cross-contamination or label mix-up
QA-026	Sampling and retain sample governance	representative lots and storage conditions	no reliable evidence for complaint investigation
QA-027	Quality metrics and trending	reject rates, complaints and excursions	risk trend not escalated
QA-028	Customer specification agreement	product limit/claim responsibility	dispute and noncompliance on release

30 | QUALITY CONTROL / PHYSICOCHEMICAL TESTING

30 distinct assessment topics • 90 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
QC-001	pH meter calibration and buffer	traceable buffers and electrode condition	incorrect cosmetic pH acceptance
QC-002	Viscometer spindle/method	geometry, speed and temperature	inaccurate texture release
QC-003	Rheometer temperature control	shear and reproducibility	false gel/emulsion characterization
QC-004	Density meter verification	temperature correction and standards	wrong fill or formulation result
QC-005	Refractometer calibration	matrix/temperature effect	incorrect soluble content result
QC-006	Moisture analyzer qualification	sample mass and endpoint	wrong powder/wax moisture
QC-007	Karl Fischer water test	interference and standard recovery	incorrect water limit
QC-008	Peroxide value determination	titration and sample oxidation	rancid oil accepted
QC-009	Acid value / saponification value	standardization and method recovery	unstable oil/soap accepted
QC-010	HPLC assay system suitability	columns, standards and separation	wrong preservative/active concentration
QC-011	GC or GC-MS perfume analysis	volatile injection and carryover	unidentified restricted impurity
QC-012	ICP-MS/OES heavy metals testing	matrix recovery and blanks	toxic metal contamination missed
QC-013	UV-Vis color analysis	reference and wavelength accuracy	wrong colorant assay accepted
QC-014	FTIR identity testing	library specificity and sampling	wrong raw material released
QC-015	Spectrophotometric SPF screening	in vitro correlation and appropriate claims	unsupported SPF acceptance
QC-016	Turbidimeter for shampoos	calibration and temperature	haze defects missed
QC-017	Colorimeter/Delta-E assay	illumination and reference standard	wrong shade approved
QC-018	Particle size analyzer	dispersion and data interpretation	incorrect pigment or mineral size
QC-019	Centrifuge physical stability screen	spin time and method validity	emulsion stability falsely predicted
QC-020	Laboratory balances	minimum weight and calibration	dilution and assay errors
QC-021	Sample labeling and custody	unique lot/sample identity	test results linked to wrong batch
QC-022	Laboratory reference standard management	shelf life and traceability	biased chemical assays
QC-023	Laboratory reagent preparation	concentration and expiry	invalid QC results
QC-024	Chemical analysis data review	integration and calculation audit trail	test failure not detected
QC-025	Stability chamber qualification	mapping, RH and alerts	invalid shelf-life evidence
QC-026	Retain sample storage	original pack and shelf condition	no credible complaint comparison
QC-027	QC outlier/trend program	signal investigation and method variation	product deterioration missed
QC-028	Raw material identity verification	sampling plan and method specificity	adulterated ingredient accepted
QC-029	Finished product net-content testing	representative packs and uncertainty	underfilled product released
QC-030	QC specifications periodic review	market and formula change mapping	obsolete limits applied

31 | QUALITY RISK MANAGEMENT / QA

20 distinct assessment topics • 60 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
QRM-001	Cosmetic QRM master procedure	risk scope and approvals	critical cosmetic risks remain unassessed
QRM-002	Product-category risk matrix	leave-on, rinse-off and user groups	inappropriate controls used for vulnerable users
QRM-003	Risk assessment initiation and triage	new product, change and event triggers	known hazards bypass review
QRM-004	Cross-functional risk review team	formulation, toxicology, production and QA input	material exposure pathway overlooked
QRM-005	Risk acceptance criteria	severity and exposure assumptions	unsafe residual risk accepted
QRM-006	Initial and residual risk distinction	verified risk-reduction evidence	ineffective actions shown as complete
QRM-007	High-severity event escalation	serious consumer harm thresholds	unsafe product continues distribution
QRM-008	Cosmetic product risk register	traceable hazard-to-control links	loss of review and owner accountability
QRM-009	Microbial contamination risk mapping	water and high-risk open steps	recurrent microbial contamination
QRM-010	Chemical contamination risk mapping	raw material and cleaning carryover	uncontrolled toxic impurities
QRM-011	Packaging compatibility risk mapping	migration and shelf-life interaction	unsafe pack-induced changes
QRM-012	Product use exposure assessment	frequency, leave-on area and target population	underestimated consumer exposure
QRM-013	Vulnerable population assessment	infants, eyes and mucosal users	higher-consequence hazards overlooked
QRM-014	Product change QRM	formulation and supplier change impact	new hazard without control strategy
QRM-015	Process change QRM	mixing time and temperature modifications	unassessed batch quality drift
QRM-016	Regulatory change QRM	ingredient restrictions and market changes	noncompliant products remain marketed
QRM-017	Risk review scheduling	product complaint and trend triggers	expired controls remain accepted
QRM-018	Risk file retention and versioning	controlled decisions and audit trail	unverifiable risk justification
QRM-019	Risk management effectiveness	action closure and recurrence evidence	persistent risks not reduced
QRM-020	Quality / occupational risk interface	product contamination from EHS incident	consumer risk overlooked following workplace event

32 | RAW MATERIALS / INGREDIENT SPECIFICATIONS

30 distinct assessment topics • 90 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
ING-001	Water-soluble surfactants	active content and microbial load	irritant or nonperforming wash product
ING-002	Nonionic emulsifiers	HLB, purity and lot variability	phase separation or irritation
ING-003	Anionic surfactants	active matter and salt contamination	viscosity and skin irritation drift
ING-004	Amphoteric surfactants	residual impurities and compatibility	increased product irritation
ING-005	Cationic conditioners	quaternary concentration and purity	irritation or adsorption issues
ING-006	Fatty alcohols and waxes	melting profile and acid values	texture and shelf-life defects
ING-007	Vegetable oils and butters	peroxide/acid value and origin	oxidative rancidity and sensitization
ING-008	Essential oils	adulteration and natural allergen fraction	sensitization or inconsistent fragrance
ING-009	Synthetic fragrances	IFRA category and allergen composition	incorrect maximum use and labeling
ING-010	Pigments and color lakes	allowed color list and heavy metals	illegal colorant or metal exposure
ING-011	Titanium dioxide ingredient	particle and market-specific inhalation review	misclassified nano/inhalation risk
ING-012	Zinc oxide ingredient	particle properties and sunscreen status	noncompliant active or dispersion
ING-013	UV filters	permitted filter list and purity	unsafe concentration or weak UV protection
ING-014	Parabens	regulated concentrations and impurities	restricted preservative noncompliance
ING-015	Phenoxyethanol	concentration and purity	excess exposure or insufficient preservation
ING-016	Organic acids preservatives	pKa and in-use pH	loss of antimicrobial performance
ING-017	Botanical extracts	identity, pesticides and microbial status	adulterated/contaminated botanical
ING-018	Clays and mineral powders	pathogen/heavy metal screening	contaminant exposure and particulate defects
ING-019	Talc	asbestos contamination risk and source testing	harmful mineral contamination
ING-020	Glycerin and glycols	identity, DEG/EG contamination and grade	toxic substitution risk
ING-021	Coloring intermediates for oxidative dyes	regulatory restriction and stability	sensitization and chemical damage
ING-022	Hair straightening chemicals	formaldehyde/releaser and exposure	chemical burns and inhalation harm
ING-023	Aerosol propellants	purity, pressure and flammability	can rupture or flammable atmosphere
ING-024	Denatured ethanol	grade, impurities and denaturant rules	harmful or noncompliant solvent
ING-025	Preservative-free raw extracts	microbial burden and holding conditions	microbial contamination propagates
ING-026	Fragrance fixatives	regulatory status and toxicity	sensitization or illegal use
ING-027	Chelators and pH adjusters	identity and concentration	incorrect pH and stability loss
ING-028	Silicones	viscosity and cyclic siloxane restrictions	texture defects or restricted ingredient
ING-029	Biopolymer thickeners	microbial load and viscosity performance	viscosity drift and preservative demand
ING-030	Supplier certificate of analysis	test adequacy and lot integrity	unverified ingredient released

33 | REGULATORY AFFAIRS / MARKET COMPLIANCE

29 distinct assessment topics • 87 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
REG-001	India product classification	cosmetic versus drug / AYUSH claims	manufacturing under wrong legal category
REG-002	India COS-8 manufacturing license scope	site and cosmetic categories authorised	unlicensed product manufactured
REG-003	India COS-9 loan-license scope	third-party and licensed premises	unauthorised outsourced manufacture
REG-004	India new cosmetic permission	new cosmetic ingredient/product trigger	required permission not obtained
REG-005	India BIS standards applicability	Ninth Schedule and applicable product IS	product fails required quality standards
REG-006	India prohibited/restricted raw materials	IS 4707 and current prohibited lists	unsafe or illegal ingredient use
REG-007	India cosmetic labeling review	manufacturer, batch, expiry and warnings	noncompliant or misleading label
REG-008	India imported cosmetic registration	product, variant and premises scope	unregistered imported product supplied
REG-009	EU responsible person appointment	EU-established RP and obligations	unlawful EU market placement
REG-010	EU product information file PIF	formula, GMP evidence, claims and safety	missing safety dossier
REG-011	EU CPSR Parts A and B	qualified assessor and exposure calculations	unsupported product safety conclusion
REG-012	EU CPNP notification	product category and formulation notification	unnotified cosmetic marketing
REG-013	EU ingredient annex screening	Annex II, III, IV, V and VI limits	prohibited or excessive ingredient
REG-014	EU fragrance allergen labeling	applicable Annex III allergen thresholds	consumer sensitization warning omitted
REG-015	EU nanomaterial notification	identity, applicable special notification	unassessed nanomaterial regulatory risk
REG-016	EU cosmetics claims substantiation	truthful and evidence-based claims	misleading marketed benefits
REG-017	UK GB responsible person	UK establishment and responsible person duties	noncompliant GB placement
REG-018	UK SCPN notification	notification and product identifiers	product sold without notification
REG-019	UK product information file	GB-specific records and safety support	incomplete market dossier
REG-020	US FDA MoCRA facility registration	eligibility, exemptions and biennial renewal	facility regulatory gap
REG-021	US FDA MoCRA product listing	listed product and annual updates	listing obligation unfulfilled
REG-022	US FDA MoCRA adverse event reporting	serious adverse event and contact routes	reportable case not investigated/reported
REG-023	US FDA cosmetic/drug boundary	sunscreen, anti-dandruff and acne claims	drug requirements not identified
REG-024	ASEAN product notification	market-by-market notification and variants	unlawful ASEAN placement
REG-025	ASEAN ingredient and label requirements	harmonized lists and local language	unsafe or mislabelled product
REG-026	Australia AICIS/TGA classification screen	cosmetic vs therapeutic claims and chemicals	wrong regulatory regime applied
REG-027	Export dossier and free sale evidence	market, testing and documentation scope	shipment rejected or misrepresented
REG-028	Regulatory intelligence review	amendments, ingredient bans and phase-outs	obsolete compliant assumptions
REG-029	Private-label responsibility matrix	brand owner, contract maker, RP and distributor	unowned safety/reporting obligation

34 | RESEARCH & DEVELOPMENT / FORMULATION

24 distinct assessment topics • 72 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
RD-001	Formulation requirement specification	product type, use and quality attributes	uncontrolled target product profile
RD-002	Active cosmetic ingredient concentration	allowed concentrations and claimed effect	irritation or unsubstantiated benefit
RD-003	Phase inversion feasibility	water/oil proportions and shear	unstable emulsion at scale
RD-004	Preservative selection strategy	pH, packaging and inoculum challenge	microbial growth in shelf life
RD-005	Preservative booster compatibility	antagonism and concentration drift	preservation efficacy loss
RD-006	Fragrance formulation compatibility	stability and allergen fraction	sensitization or odor drift
RD-007	Colorant selection and shade stability	permitted pigments and fade	noncompliant color or shade complaint
RD-008	Thickener polymer hydration	addition order and hydration time	lumps or viscosity defects
RD-009	Antioxidant and chelator selection	oxidation pathways and ingredient compatibility	rancidity or discoloration
RD-010	pH range development	buffer capacity and efficacy of preservative	microbial or irritation risk
RD-011	Thermal cycling screening	heat/cold tolerance and phase change	separation during distribution
RD-012	Freeze-thaw testing	crystallization and packaging stress	product texture/pack failure
RD-013	Accelerated stability testing	meaningful conditions and validated endpoints	wrong shelf-life estimate
RD-014	Real-time stability protocol	climate zones and test intervals	expiry period not substantiated
RD-015	Photo-stability testing	UV exposure of pack and formula	color and fragrance degradation
RD-016	Product-pack compatibility trial	migration and closure interaction	material degradation or leaching
RD-017	Pilot batch scale-up risk	mixing power per volume and heat transfer	commercial batch non-equivalence
RD-018	New ingredient evaluation	supplier changes and impurity risk	unstudied component introduced
RD-019	Alternative preservative strategy	challenge test under product matrix	inadequate antimicrobial protection
RD-020	Water activity feasibility	a_w and microbial growth suitability	incorrect low-risk classification
RD-021	High-alcohol product formulation	alcohol concentration and flammability	insufficient stability or worker fire risk
RD-022	Sensory testing design	representative panel and blinded evaluation	biased claims and quality decisions
RD-023	Consumer-use simulation study	dispensing and contamination behavior	in-use spoilage underestimated
RD-024	Process robustness / DoE	critical material and process variability	sensitive formulation unrecognized

35 | SERUMS / GELS / ACTIVES

18 distinct assessment topics • 54 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
GEL-001	Carbomer wetting and dispersion	addition rate and clump control	gel nonuniformity
GEL-002	Carbomer neutralization	pH and neutralizer concentration	irritation or unstable gel
GEL-003	Hyaluronic acid hydration	shear and viscosity development	polymer degradation
GEL-004	Niacinamide stability	pH and temperature	discoloration or irritation risk
GEL-005	Vitamin C serum oxidation	oxygen/light and pH	potency/appearance loss
GEL-006	Retinoid cosmetic formulation	permitted derivative and exposure	photo-instability or restricted-use violation
GEL-007	Alpha hydroxy acid dosing	free acid, pH and consumer warnings	chemical burns / irritation
GEL-008	Beta hydroxy acid dosing	concentration and legal classification	skin irritation or drug-category issue
GEL-009	Enzyme-containing serum stability	proteolysis and pH	loss of performance or sensitization
GEL-010	Botanical gel extract addition	microbial status and preservative demand	microbial spoilage
GEL-011	Hydroalcoholic gel processing	flammability and solvent loss	unexpected concentration drift
GEL-012	Thixotropic serum rheology	shear and viscosity recovery	poor pumpability and shelf stability
GEL-013	Layering of dual-phase serum	phase ratio and dispensing	uneven component dose
GEL-014	Hydrogel air entrapment	vacuum and curing conditions	bubbles, poor appearance and dosage
GEL-015	Dropper bottle compatibility	glass, rubber bulb and extractables	contaminants migrate into serum
GEL-016	Serum batch light protection	photosensitive ingredient exposure	degradation during processing
GEL-017	Serum preservative penetration	pack opening and re-inoculation	consumer-use contamination
GEL-018	High-viscosity serum filling	pump shear and nozzle accuracy	wrong dose and air pockets

36 | SHAMPOOS / FACE WASH / BODY WASH

20 distinct assessment topics • 60 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
SURF-001	Surfactant base dilution	active matter and water quality	over-irritant or weak cleanser
SURF-002	Surfactant addition order	foaming and salt curve	uncontrolled viscosity
SURF-003	SLES / betaine blending	active concentration and compatibility	skin irritation or phase split
SURF-004	Salt thickening curve	NaCl dosage and viscosity peak	sudden viscosity collapse
SURF-005	Pearlescer dispersion	temperature and mixing	sedimentation and visual defects
SURF-006	Foam booster dosage	skin irritancy and formula stability	harsh product or haze
SURF-007	Opacifier dispersion	mixing and particle settling	nonuniform opacity
SURF-008	Anti-dandruff claim classification	jurisdiction-specific drug active rules	cosmetic/drug noncompliance
SURF-009	Shampoo pH adjustment	scalp safety and preservative activity	irritation or microbial growth
SURF-010	Fragrance solubilization	solubilizer ratio and cloud point	separation or allergen pockets
SURF-011	Cold process mixing	adequate dissolution and hold time	undissolved particles
SURF-012	Hot process mixing	surfactant stability and evaporation	concentration drift
SURF-013	Surfactant microbial hold	water activity and preservation	in-process microbial expansion
SURF-014	Face wash exfoliant particle control	particle size and abrasion	physical skin injury
SURF-015	Baby wash ocular safety	eye irritation and mild surfactants	eye irritation in infants
SURF-016	Sensitive-skin wash allergen screen	fragrance and color limits	sensitization in vulnerable users
SURF-017	Shampoo pump foaming consistency	pack/surfactant interaction	dispense failure and microbial entry
SURF-018	Shower gel color stability	oxidation, pH and light	discoloration and nonconformity
SURF-019	Body wash viscosity after aging	high/low temperature changes	leakage or dispense failure
SURF-020	Liquid detergent/cosmetic boundary	product intended body use and claims	wrong consumer-use classification

37 | SUNSCREENS / UV PROTECTION

22 distinct assessment topics • 66 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
SUN-001	Market classification for sunscreen	US OTC drug vs EU/India cosmetic	incorrect market legal obligations
SUN-002	Permitted UV filter screening	EU Annex VI and local allowed list	illegal/restricted sunscreen formulation
SUN-003	UV filter raw material particle size	dispersion and inhalation characteristics	poor SPF or nano hazard
SUN-004	Inorganic UV filter premix	deagglomeration and wetting	nonuniform UV protection
SUN-005	Oil-phase organic UV filter solubility	solubility limit and temperature	crystal formation and SPF drift
SUN-006	Photostability of UV-filter blend	exposure and interaction	loss of protection under sunlight
SUN-007	SPF in-vivo test design	ISO method and representative batch	misleading SPF claim
SUN-008	UVA assessment methodology	UVA protection and test route	unsubstantiated broad-spectrum claim
SUN-009	Water-resistance claim testing	standard and reapplication label	unsupported protection promise
SUN-010	UV filter chemical assay	identity and quantitative uniformity	under-dosed protection
SUN-011	SPF formulation homogeneity	mixing and sampling location	batch-to-batch unequal protection
SUN-012	Tinted sunscreen pigment dispersion	pigment sizing and shade	uneven tint/coverage
SUN-013	Sunscreen viscosity under heat	stability and flow	physical separation reduces protection
SUN-014	Airless sunscreen pump performance	dosage and sealing	inaccurate delivery or contamination
SUN-015	Sunscreen packaging light barrier	UV permeability and formula degradation	protection loss during shelf-life
SUN-016	Nanomaterial labeling and dossier	EU nano identification and rules	incomplete safety/notification assessment
SUN-017	Child sunscreen safety assessment	user age and application frequency	underestimated child exposure
SUN-018	Sunscreen fragrance/photosensitizer review	phototoxicity and allergen content	sun-triggered skin reaction
SUN-019	Sunscreen in-use reapplication instructions	application amount and use frequency	consumer underprotection
SUN-020	SPF label market comparison	test methods and local claim rules	non-compliant international artwork
SUN-021	Sunscreen product stability after freeze thaw	phase separation and filter migration	SPF variability on use
SUN-022	Sunscreen filled pack torque test	seal and leakage	pack failure affecting product protection

38 | TOOTHPASTE / TOOTH POWDER / MOUTH PRODUCTS

18 distinct assessment topics • 54 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
ORAL-001	Toothpaste abrasive raw material	particle size and impurity	enamel abrasion or contamination
ORAL-002	Fluoride ingredient classification	market rules and allowed concentration	toxic dose or unlawful medicinal claim
ORAL-003	Toothpaste humectant blending	viscosity and DEG/EG contamination	toxicity or texture defect
ORAL-004	Thickener hydration before abrasive	agglomerates and dispersion	uneven toothpaste texture
ORAL-005	Abrasive dosing accuracy	mass and mixing homogeneity	excess dental abrasion
ORAL-006	Toothpaste flavor mixing	mint/essential oil allergens and exposure	oral irritation
ORAL-007	Toothpaste sweetener dosing	identity and concentration	unintended exposure or poor palatability
ORAL-008	Toothpaste preservative efficacy	oral matrix compatibility and pH	microbial growth in tube
ORAL-009	Toothpaste deaeration	vacuum cycle and foaming	voids and unstable fill weight
ORAL-010	Toothpaste bulk transfer	closed transfer and hold time	contamination during transfer
ORAL-011	Tube filling and crimping	seal integrity and fill volume	leakage and contamination
ORAL-012	Toothpowder dry blending	ingredient identity and fine dust	incorrect abrasive or inhalation hazard
ORAL-013	Whitening toothpaste claims	peroxide and market restrictions	unlawful/unsafe tooth-whitening claim
ORAL-014	Mouth rinse alcohol concentration	ethanol assay and child exposure	unexpected ingestion risk
ORAL-015	Mouth rinse color/flavor approval	oral-use ingredient restrictions	irritation or oral toxicity
ORAL-016	Toothpaste microbial release testing	neutralization and product matrix	false negative microbial results
ORAL-017	Toothpaste shelf-life verification	fluoride availability and pack interaction	unsubstantiated efficacy / expiry
ORAL-018	Toothpaste tube material compatibility	aluminum/plastic interaction	degraded paste or metal contamination

39 | VALIDATION / QUALIFICATION / CALIBRATION

26 distinct assessment topics • 78 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
VAL-001	Validation master plan	site/product critical systems and roles	unjustified unvalidated controls
VAL-002	Equipment URS and risk traceability	functional/critical requirements	inadequate equipment design
VAL-003	Design qualification of product-contact systems	cleanability and material suitability	built-in contamination pathways
VAL-004	Installation qualification of mixers	installed services and material verification	incorrect equipment configuration
VAL-005	Operational qualification for mixers	speed, heat and vacuum limits	uncontrolled process settings
VAL-006	Performance qualification for cream process	representative worst-case and scale	unstable commercial batch
VAL-007	Filling machine qualification	accuracy across viscosities and container sizes	incorrect net content
VAL-008	Sealing machine qualification	temperature/pressure/time windows	leak-prone packaging
VAL-009	Temperature-mapping qualification	locations and seasonal loads	shelf-life excursions missed
VAL-010	Water system commissioning	microbial, chemical and distribution evidence	inadequate process water
VAL-011	HVAC qualification for cosmetic production	risk-based conditions and airflow	dust or microbial transfer
VAL-012	Compressed air quality qualification	oil, water and particles	chemical and foreign matter contamination
VAL-013	Cleaning verification/validation	worst-case residues and recovery	residual allergen/pigment contamination
VAL-014	Hold-time validation for bulk	microbiology and physico-chemical stability	bulk degrades before filling
VAL-015	Stability protocol qualification	real/accelerated conditions and relevance	unfounded shelf life
VAL-016	Preservation efficacy verification	product/matrix and pack interactions	microbial growth in use
VAL-017	Calibration master list management	equipment criticality and due dates	measurement uncertainty ignored
VAL-018	Out-of-calibration impact	affected lots and retrospective review	unsafe batch decision based on false measurement
VAL-019	Preventive maintenance effectiveness	equipment fault trends and product impact	repeat mechanical defects
VAL-020	Software configuration qualification	recipe and weighing safeguards	incorrect batch instructions
VAL-021	Analytical method verification	specificity, accuracy and robustness	false release results
VAL-022	Transport validation of finished packs	route/temperature and shock	damaged or leaking stock
VAL-023	Requalification following maintenance	impact to critical components	changed equipment control unverified
VAL-024	Process capability trend	critical attributes and batch variability	drift in product quality unnoticed
VAL-025	Cleaning hold time verification	post-clean storage environmental controls	biofilm or recontamination
VAL-026	Scale-up transfer qualification	shear, heat and mixing equivalence	formula not reproducible at scale

40 | WAREHOUSE / MATERIAL CONTROL

27 distinct assessment topics • 81 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
WH-001	Goods receipt and visual inspection	transport damage and seal check	contaminated or wrong material received
WH-002	Incoming material quarantine status	segregation before QC disposition	untested ingredient issued
WH-003	Raw material barcode assignment	batch/lot and correct INCI identity	material misidentification
WH-004	Identity sampling of ingredients	representative sample and cross-contamination	unverified ingredient accepted
WH-005	Sampling booth cleaning and controls	air flow and material carryover	cross-lot contamination
WH-006	Approved/rejected material segregation	physical status and ERP alignment	rejected material inadvertently used
WH-007	Temperature-sensitive fragrance storage	temperature and closed pack	loss of volatile profile
WH-008	Oil and butter storage	oxygen/light and temperature	oxidation and rancidity
WH-009	Preservative ingredient stock control	expiry and container integrity	degraded preservative introduced
WH-010	Hazardous and flammable storage	segregation and fire safety	fire or unsafe solvent release
WH-011	Pigment storage and dust control	moisture and color segregation	caking/cross-shade contamination
WH-012	Intermediate and bulk storage	hold-time, cover and status	bulk microbial contamination
WH-013	Bulk transport totes	cleaning and sealed transfer	contamination during warehouse transfer
WH-014	FEFO / shelf-life management	release and expiry date	expired ingredient used
WH-015	Material dispensing from warehouse	formula pick accuracy	wrong or excessive ingredient
WH-016	Material return to stock	reclosure and original lot status	used/untraceable raw material reissued
WH-017	Repackaging and relabeling raw materials	traceability and suitable containers	identity loss or migrated chemical
WH-018	Pest monitoring in warehouse	trap trends and ingress paths	animal/foreign material contamination
WH-019	Temperature mapping and monitoring	representative hot/cold storage points	degradation not detected
WH-020	Distribution of packaging components	printed artwork version control	old/inaccurate packaging used
WH-021	Spillage and damage response	quarantine and exposed batches	contaminated items enter use
WH-022	Cold room failure response	alarm and quality impact assessment	temperature-labile material spoiled
WH-023	Warehouse cycle count and reconciliation	transaction accuracy	lot genealogy incomplete
WH-024	Contract warehouse qualification	storage specs and QA agreement	uncontrolled third-party conditions
WH-025	Material sampling and batch linkage	sample label and traceability	incorrect release or test attribution
WH-026	Materials return from contract packer	lot genealogy and status	mixed/reworked stock released
WH-027	Stock destruction and disposal	authorization and reconciliation	rejected material reenters supply

41 | WATER TREATMENT / PROCESS WATER

24 distinct assessment topics • 72 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
WATER-001	Incoming municipal or bore water	chemical/microbial source variability	contaminated process-water feed
WATER-002	Potable water pretreatment	feed filtration and monitoring	upstream burden overwhelms treatment
WATER-003	Multimedia filter integrity	filter differential pressure/backwash	biofilm or particulate breakthrough
WATER-004	Activated carbon bed sanitation	biofilm control and chlorine removal	microbial growth in water train
WATER-005	Softener resin performance	hardness breakthrough	scale and formulation instability
WATER-006	Water RO membrane integrity	conductivity and rejection rate	salts or microbial passage
WATER-007	RO sanitation cycle	chemical contact and rinse	microbial colonization and cleaning chemical carryover
WATER-008	UV lamp treatment	intensity and maintenance	ineffective microbial reduction
WATER-009	Ozone sanitation process	dissolved ozone dose and removal	unsafe residual or ineffective disinfection
WATER-010	EDI/deionization control	conductivity and resin health	unreliable process-water quality
WATER-011	Storage tank headspace ventilation	filter and condensation	airborne contamination of water
WATER-012	Water loop temperature and recirculation	dead legs and stagnant zones	biofilm growth
WATER-013	Water outlet sampling plan	worst points and schedule	localized contamination missed
WATER-014	Point-of-use hose management	sanitation and drain-down	biofilm contaminates batch
WATER-015	Water test alert/action levels	viable counts and trends	unsafe quality drift not acted on
WATER-016	Water microbiology test method	incubation and sample hold	false negative contamination result
WATER-017	Conductivity/TOC instrumentation	calibration and sensor drift	inaccurate water quality disposition
WATER-018	Water piping material selection	leaching and weld hygiene	chemical/microbial contamination
WATER-019	Water system maintenance isolation	post-maintenance sanitization	contaminant introduced to plant
WATER-020	Water system emergency shutdown	backup supply and quality release	uncleared water used in production
WATER-021	Reverse flow prevention	backflow and cross connection	contaminated water returns to utility
WATER-022	Water tank cleaning validation	biofilm removal evidence	persistent microbial source
WATER-023	Water seasonal change assessment	source temperature and microbial changes	water program not fit for season
WATER-024	Water used for baby/eye products	microbiological specification by risk	higher-risk cosmetic contamination

42 | WET WIPES / MASK SHEETS / PADS

15 distinct assessment topics • 45 associated risk scenarios in the Excel register

Review each applicable activity at actual equipment/product level, with documented impact and approved controls. Where not applicable, retain a justified exclusion.

Topic ID	Equipment / process / activity	Critical parameter / failure control	Potential quality / safety consequence
WIP-001	Nonwoven substrate qualification	fiber impurities and shedding	foreign fibers on skin
WIP-002	Wet wipe lotion preparation	preservative and pH	microbial growth during use
WIP-003	Impregnation liquid dosing	solution loading and uniformity	dry wipes or overexposure
WIP-004	Wet wipe saturation residence time	bulk exposure and sanitation	microbial growth in equipment
WIP-005	Wipe folding machine hygiene	contact surfaces and sanitation	substate contamination
WIP-006	Wet wipe pouch sealing	barrier performance and leak rate	dry product or microbial ingress
WIP-007	Resealable wet-wipe lid fit	consumer reuse seal performance	evaporation or contamination
WIP-008	Baby wet wipe sensitization review	fragrance, alcohol and preservative	infant irritation
WIP-009	Makeup remover pad surfactant dosage	eye exposure and residue	eye irritation
WIP-010	Sheet mask essence compatibility	mask substrate and preservative	loss of preservation effectiveness
WIP-011	Sheet mask folded placement	contact surfaces and foreign material	contaminated facial product
WIP-012	Wet-wipe challenge test suitability	substrate extraction and method	false preservation efficacy
WIP-013	Wet wipe in-use simulation	multiple opening and closure	microbial contamination in pack
WIP-014	Wet wipe expiry assessment	water loss and preservative stability	product spoilage before expiry
WIP-015	Preservative-free wipes claim review	microbiological risk classification	misleading claim and inadequate control

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