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Document History Log

Any modification to the document must be reviewed and approved as per the corporate policies and procedures of document control

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1. Introduction

Dubai Municipality, Health & Safety Department prepared this guideline based on Local Order No. 11, 2003 on public health and Safety in the Emirate of Dubai

The purpose of this guideline is to improve the free movement of Cosmetic & personal care products within Dubai, while ensuring a high level of safety and protection of human health.

2. Objectives

The purpose of this guideline is to improve the functioning of Dubai market through the harmonization of the rules on the making available on the market and the use of Cosmetic & personal care products, while ensuring a high level of protection of both human health and the environment. Cosmetic & personal care products should neither be made available on the market nor used unless authorized in accordance with this Regulation.

3. Legislations

It is difficult for Dubai Municipality to perform its duties and specialties as an institutional organization without having a legislative system that regulates its activities, draws the framework of its relationship with the local community and gives legitimacy to its actions. Therefore, the decree issued regarding the municipality foundation has contained a provision on giving it the authority and power to issue orders, regulations, and decisions. Current legislative law that applies to Cosmetic & personal care products found in: Legislative order No. 30/2007 and local order No. 11/2003 concerning Public Health and Safety of the society in the Emirate of Dubai.

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4. Definitions

Definition	Meaning
Registration	Since permit and registration section is the primary principle of cosmetics registration, its process allows the permit and registration section to gather adequate information to assess the safety of cosmetic & personal products. It is necessary to emphasize that no cosmetic product shall be manufactured, imported, exported, advertised, sold, or distributed in Dubai unless it has been registered in accordance with Dubai Municipality (DM) regulation.
The Registration Regulation	The Dubai Government regulates the manufacture, sale, and importation of cosmetic & Personal care products by requiring that all these products to be registered prior to placing in Dubai market; as well by requiring the individuals running the activities related to cosmetics to be licensed in Dubai.
Cosmetic and Personal care Product	A cosmetic product shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition.
Importer / Manufacturer	A person or persons (including an association or partnership) who, under their own name, or under a trade, design or word mark, trade name or other name , work or mark controlled by them , import , manufactures and/or sell a cosmetic & personal care product. This includes importers or retailers and manufacturers who control the cosmetic & personal care products in question.

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D	efinition	Meaning		
Distributors		Means any natural or legal representative in the supply chain, other than the manufacturer or the importer, who makes cosmetic & personal care products available on the market.		
	Agent	A representative who acts on be organizations, to handle business affair		eople or
Establishment Any building(s), or area(s), fixed or mobile, in which cosmetic a personal care products are handled (displayed or stored).			netic and	
Any tag, brand, mark, pictorial or other descriptive matter, writLabelprinted, stenciled, marked, embossed, or impressed on, or attacto a container of cosmetic & personal care products.				
Claim Medical claim		Any message or representation, which local regulations, including pictori representation, in any form, which stat a cosmetic & personal care products ha	al, graphic or es, suggests, or im	symbolic plies that
		Claim that cosmetic & personal care pro prevent, cure, diagnose, or alleviate a di	_	
Hea	lth Warning	Describe a relationship between a cosm or its ingredients, and health- related co	-	e product
Advertisement		Promoting cosmetic & personal care p selling or dispersing it directly or indir visual form, or another way.		
	Sample	Original piece of product in which wil market.	ll be presented in	the local
Ingredient		A Chemical substance and its even nature another to give final consumer product.	-	ixed with

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5. Scope & Cosmetics Classifications

***** Functions for Cosmetics Products:

- To clean
- To perfume
- To change the appearance
- To protect
- To keep in good condition
- To correct body odors

The Field of Application of Cosmetics:

- The epidermis
- The hair system
- The nails
- The lips
- The external genital organs
- The teeth and mucous membranes of the oral cavity.

5.1 Products Categories (within the scope)

> Skin care products:

- Body care preparations:

Examples: Body Creams, emulsions, lotions, gels and oils, bath, and shower preparations (salts, foams, oils, gels, etc.), Deodorants and anti-perspirants & Products for external intimate hygiene.

Face & Neck Preparations

Examples: Face cream, serum, oil, gel, mask, foam, mist for the following purpose: anti-aging & lifting, Skin-whitening, purifying, glowing, moisturizing, hydrating, nose strips, aftershave products, after sun products, etc.

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- Hand care

Examples: Hand soap, cream, serum, mask, oil for the following purpose: cleansing, skinwhitening, moisturizing, hydrating, nourishing, etc.

Foot care

Examples: Foot soap, cream, mask, salt for the following purpose: cleansing, peeling, skinwhitening, moisturizing, hydrating, nourishing., etc.

Eye care

Examples: Eye cream, serum, mask for the following purpose: moisturizing, hydrating, antiaging, dark circle cream. & Eye makeup remover.

- <u>Lip care</u>

Examples: Lip balm, lip mask, lip tint ..etc.

- <u>Makeup products</u>

Examples: primer, Tinted foundation/powder, setting powder, setting spray, eye shadow, eye liner, eyebrow tint, eyebrow pencil, lip liner, lipstick, lip gloss, highlighter, bronzer,etc.

- <u>Sunscreen & suntan preparations</u>
 Examples: Face & body sunscreen cream, lotion, spray, tanning lotion, after sun products.
- <u>Shaving products</u>
 Examples: Shaving gel, cream& foam.

- <u>Depilatories</u>

Examples: wax strips, hair remover cream, hair removal spray & wax.

Nail & cuticle products:

Examples: Nail polish, gel, dip gel, nail oils, cuticle oil & nail polish remover.

> Oral Hygiene products:

Examples: Mouth & tooth wash, paste, spray for the following purpose: cleansing, whitening refreshing, protection.

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Baby products:

Examples: Baby shampoo, lotion, cream, oil, powder, wipes, etc.

Hair & scalp products:

Examples:

- Hair shampoo, dry shampoo, conditioner, mask & oil
- Scalp exfoliate.
- Hairdressing products (lotions, brilliantines, spray, wax)
- Hair dyes & bleaching products
- Product for straightening hair (hair Botox, keratin, protein., etc.)
- Hair waving products.

Professional use products:

Products in this category are not used for retail market and directly used by experts at beauty centers, clinics & spa.

Note: The sentence 'For Professional use only' should be clearly indicated on the product label.

B2B products:

Products in this category are not used for the retail market and directly Business to Business marketing.

Hotels amenities products:

Products in this category are produced for hotel amenities only and are not available in the retail market.

Examples: Hair shampoo, conditioner body wash, lotion ..etc

5.2 Products Categories (out of the scope)

Product indicated to prevent, cure, diagnose, or alleviate a disease or its symptoms.

Examples

- Acne products
- Eczema, Psoriasis, Dermatitis treatment
- Rosacea, weaken & damaged capillaries treatment.
- Relieve tired swollen, heavy legs Varicose veins.
- Hair loss & alopecia

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Product containing substances which restore, correct, or modify physiological functions by exerting a pharmacological, immunological, or metabolic action.

Examples

- Hair & eyelash re-growth
- Product to treat dry mouth.
- Breast augmentation products
- Products for bruises, swellings, bumps
- Products intended to simulate wounds, scars, warts.
- Product containing substances which improve microcirculation & lymphatic drainage.
 - > Product intended to be used with invasive techniques.

Examples

- Products used by Mesotherapy technique such as meso-roller, derma roller, dermapen & other similar techniques.
 - Product intended to be used with special device to induce a deeper penetration.
 <u>Examples</u>
- Product intended to be delivered through iontophoresis or similar mechanisms.
 - Products are not considered to be a cosmetic product/ intended indication is NOT fall under cosmetic scope.

Examples

- Products are intended to stimulate sexual activity.
- Products are intended to relieve joint & muscles pain.
- Product to treat dry mouth.
- Products against head lice
- Products against nail biting
- Products are indicated to uses as massage oil (Primary or main function as a massage product)
- Products are intended to improve breathing & sleep.
- Products are intended to have spiritual mental effects/claims (ex: calming, uplift mood, inner peace, improve focusing, meditationetc)
- Nail glue & Eyelash glue
- Product is intended to be used as a vaginal wash (due to application site)
- Products are intended to be used as a nasal spray.

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6. Safety & Quality Specifications

Cosmetics shall:

- Not contain any other active substances except those stated on the label.
- Not contain any human part substance derived from any part of the human body.
- Not exceeding the limits for microbial contamination and toxic heavy metals as specified in Annex 1.
- Not contain any substance above the limit specified in the list of restricted substances.
- Be of acceptable standards of quality in terms of product stability, have adequate shelf-life period, proper packaging, and labeling, and are manufactured according to Good Manufacturing Practice (GMP) standard.
- Not manufactured or held under sanitary conditions whereby it may have become injurious to users or contaminated with filth.

7. Product Label Principles

7.1 Required Label Components

The followings are the required components that must be declared in clear English and/or Arabic language:

- Brand Name: A trademark or trade name.
- **Product Name:** A trademark or trade name cannot be used to replace the name of the Product.
- Manufacturer detail: Name, Address, Web address of Manufacturer or Agent acting in UAE.
- **Country of Origin:** should be clearly indicated to avoid any misleading for the customers, should be clearly mentioned as (e.g. Made in , Manufactured in , Packed in United Arab Emirates. USA, France ...etc)
- Ingredients: Name of active and inactive ingredients (in INCI names or Botanical names)
- Pack size
- **Production & Expiry Dates:** must be clearly indicated on the label using non-removable printing or non-removable stickers.

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- **Storage Condition:** to be clearly indicated mentioning any other specific storage conditions than normal if any.
- Instruction of Use: recommended daily dosage should be clearly indicated.
- Product indications / intended use.
- General warning: it can be general or specific to the product type/ingredient.
- Identification Code: (Barcode) to be clear and unique for each product.
- Batch Number: batch or Lot identification number to be indicated clearly on the label.
- Special symbol (if applicable)
- Hour-Glass-Symbol (The date of minimum durability indicated by "best before end")
- The period after opening Symbol.



- Enclosed Leaflet Symbol (If it is impossible for practical reasons to print on the packaging all the conditions of use and warnings, an enclosed leaflet, label, or tape must be provided, and the following symbol has to be on the packaging)
- Dangerous Substances (Symbols must be employed if the substance can be defined as explosive, oxidizer, flammable, harmful, toxic irritant, corrosive, or harmful to environment).
 Note:

The marking and labeling of additional substances, including implementing the classification, labeling, and packaging requirements for chemicals based on the United Nation's Globally Harmonized System.

- Other symbols/logos (ex: Eco-Label, Vegan, Certified organic, HALAL. CE mark...etc).
- <u>Note:</u>

The following components should not be available on the product label:

- ➡ Inconsistent Illustrations: Pictures and illustrations which are inconsistent with the prevailing social customs and values shall not be used.
- ➡ Medical Claims: any claims related to prevention, treatment or curing of any type of disease must not be presented or referred to on the labels, brochures, leaflets or advertisements or in any other way.

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7.2 Misbranding

A cosmetic may be deemed misbranded for reasons of:

- False or misleading labeling.
- Failure to state prominently and conspicuously any information required by or under authority of this act.
- Misleading container presentation or fill.

8. Registration of Cosmetic & Personal Care Products

Since consumer safety is the primary principle of Cosmetics registration, its process allows the Registration and Permits Section to gather adequate information to assess the safety of cosmetic & personal care products . It is necessary to emphasize that no Cosmetic product shall be manufactured, imported, exported, advertised, sold or distributed in Dubai unless it has been registered in Montaji system in accordance with Dubai Municipality regulation.

According to the Local Order No. 11 / 2003. Dubai Municipality regulates the manufacture, sale and importation of cosmetics and Personal care by requiring that all products to be registered prior to placing in

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Dubai market; as well by requiring the individuals running the activities related to Cosmetics to be licensed in Dubai or other emirates.

To apply for the service:

- Login to <u>www.montaji.dm.gov.ae</u>
- Choose Services
- Consumer Product Registration Service (Montaji)
- Run Service.

8.1 Who Should Apply for Registration?

Individuals who import or locally manufacture Cosmetic products & Personal care, or have products imported or manufactured on their behalf are responsible for applying to have their products registered. The following should make an application for registration of a Cosmetic product:

o Local Manufactures:

Local manufacturers in Dubai are advised to contact the Registration & Permits Section for proper registration of Cosmetic & Personal care, Agents of local manufacturers are to take the necessary steps to ensure that the products intended for the Local market are registered before the manufactured products are placed into Dubai market.

• Foreign Manufactures:

The importer who is responsible for all matters pertaining to the registration of the product is advised to contact Health and Safety Department – Registration and Permits Section at Dubai Municipality for registration.

o <u>Agent:</u>

Agents of foreign manufacturers are to take the necessary steps to ensure that Cosmetics intended for the local market are registered before consignments of such products are imported to Dubai.

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8.2 Criteria of Applicant

Applicant for product registration must be a company incorporated in Dubai or have a warehouse in Dubai and having a trade license in Dubai indicating activities related to Cosmetics.

8.3 Responsibility of Applicant

- The applicant shall be responsible for the product, its safety, performance, and all information supplied in support of his application for registration of the product.
- The Cosmetic placed on the market must not cause damage to human health when applied under normal
 or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation,
 its labeling, instructions for its use and disposal, warning statements as well as any other indication or
 information provided by the manufacturer or his authorized agent or by any other person responsible for
 placing the product on the market.
- The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Guideline.

8.4 Amendments or Change in Registration Particulars

After a Cosmetic Product has been registered, any subsequent amendment in particulars of the application relating to the Cosmetic product must be notified or approved by the Registration and Permits Section.

8.5 Validity of Product Registration

The registration of a Cosmetic product shall be valid for 5 years as extension for renewal to be reviewed.

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9. Required Documents for Registration of Cosmetic & Personal Care Products (Product Dossier)

To proceed with registration of a Cosmetic Product with Dubai Municipality – Health & Safety Department – Registration & Permits Section, the product must fulfill all the below documents:

9.1 Free Sale Certificate (FSC)

A document to indicate that the Cosmetics are legally sold or distributed in the market freely without restriction in the country of origin. This certificate must be issued by the regulatory authorities in the country of origin (e.g. health authorities or recognized bodies such as Chamber of Commerce), and should be valid at the time of submission and request.

Note:

If the product name to be marketed in Dubai is different from the FSC, confirmation letter from product owner is required and should be attested by a government authority in the country of origin.

9.2 Ingredient report

A document to declare in details all the ingredients in chemical name and Chemical Abstracts Service CAS (for chemical ingredient only, e.g. preservatives etc.) in weight. This certificate must be issued by the manufacturer in the country of origin of the product. It should be signed and stamped by the R&D department in at the manufacturer.

9.3 Good Manufacturing Practices (GMP: ISO 22716)

A document to defines quality measures for both production and quality control and defines general measures to ensure that processes necessary for production and testing are clearly defined, validated, reviewed, and documented, and that the personnel, premises and materials are suitable for the production of Cosmetics.

Note:

This certificate is requested for local manufacturer; must be issued from certified bodies and needs to be valid at the time of submission.

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9.4 Laboratory Test Report

A document to declare in details the result of laboratory test for Cosmetic product. This report needs to be issued by a certified lab and accredited test methods.

A detailed list of laboratory tests will be listed in Annex 1.

9.5 Other documents

Any other document may be requested during the registration process when necessary.

Examples:

- HALAL certificate needs to be issued from recognized Islamic society in the country of origin.
- Note:
- This certificate is mandatory if Halal logo is present on the label and needs to be valid at the time of submission.
- Organic/Vegan certificate, to indicate the source ingredient and needs to be issued from recognized bodies in the country of origin.
- Clinical studies to proof certain claims or statistics mentioned on the label, and needs to be issued from recognized bodies in the country of origin.
- Safety assessment report for a specific ingredient in the combination and/or for the overall product.

9.6 Special cases

The following is additional requirements for some cosmetic and personal care products:

- Cannabinoid-Based Cosmetics: if the applied product contains hemp oil (INCI: Cannabis Sativa Seed Oil) or cosmetic oil with CBD (INCI: Cannabidiol), then the applicant/ manufacturer should provide the INCI name of ingredient and must demonstrate that their finished products are <u>free from</u> <u>tetrahydrocannabinols (THC)</u> by tetrahydrocannabinol content testing in accredited laboratories.
 *Illustration picture of Cannabis sativa leaves should NOT be indicated on the product label (inconsistent with the DM regulation).
- Fluoridated toothpaste/oral care product: If the product label listed a form of fluoride as an ingredient, e.g., sodium fluoride, stannous fluoride or sodium monofluorophosphate fluoridated toothpaste, which is

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produced through the addition of sodium fluoride monofluoro¬phosphate, stannous fluoride, and similar fluoride compounds, in the management of dental caries, then the applicant/ manufacturer should provide total fluoride content by testing in Dubai central lab or any accredited laboratories.

• Skin peeling product (Alpha-hydroxy acids based products)

If the applied cosmetic product contains Alpha-hydroxy acids (Citric acid; Glycolic acid; Lactic acid. Malic acid; Mandelic acid; Tartaric Acid...etc) the applied product must comply with the following criteria:

- The final product has a <u>pH of 3.5 or greater (retail use) & pH of 3 or greater (professional use</u>
 ONLY)
- -The following precautions should be indicated on the label:
 - Use only as directed.
 - Avoid contact with the eyes.
 - If irritation persists, discontinue use, and consult a physician.
 - It is recommended that prior to exposure to the sun, users cover areas where AHAs have been applied with sunscreen.
 - \circ $\;$ Contact of the product with the skin must be of limited frequency or duration.

10. Importation of Cosmetics

Cosmetic categories shall be registered prior to import or export process (refer to Consumer products Import and Re-export procedures and requirement guideline).

11. Market Compliance & Enforcements

11.1Market control action

Consistent with Dubai municipality regulation of Cosmetics, the Dubai Municipality is authorized to require premarket approval through current registration program (Montaji).

Market compliance assured by establishments' inspection program covers the following:

• Status of product registration

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- Physical conformity of products
- Sampling for related laboratory testing

Dubai Municipality is responsible to ensure health and safety of products that are traded or promoted in local market of Dubai and action will be considered as per the current enforced rules for violated establishments and products.

11.2 Advertisement

Any related advertisement or promotional activity needs pre-approval through (Montaji system), for examples: brochures, newspaper& magazines, promotional campaigns, social media, TV & media, outdoor and indoor advertisements.

Note:

The following cases does not require Dubai Municipality approval:

- Product sales subject to conditions, gifts, prizes, discount coupons, etc.
- Free distribution of products or samples of registered products.

11.3 Product Recall & Withdrawal

The product recall & withdrawal is promptly and efficiently retrieving Batch/ Bar Code of the product that does not comply with health and safety requirements, or that may have an undesirable effect on consumers. Recalls & withdrawal can be initiated at the request of the Dubai Municipality, or other relevant authorities to recall the product.

11.4 Violations & Penalty

Individuals who contravene any of the provisions of the guidelines and regulations will be charged as violated by Local Order No. 11 / 2003.

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12. References

- Local Order No. 11 / 2003 on public health and Safety in the Emirate of Dubai
- GSO 1943:2016 : Safety Requirements of Cosmetics and Personal Care Products.
- REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF
- THE COUNCIL.
- MANUAL OF THE WORKING GROUP ON COSMETIC PRODUCTS (SUB-GROUP ON BORDERLINE PRODUCTS) ON THE SCOPE OF APPLICATION OF THE COSMETICS REGULATION (EC) NO 1223/2009 (ART. 2) V.5.2.
- HEALTH CANADA : Cosmetic Ingredient Hotlist

For (suggestions, comments, and complaints)	For further information
 Unified interactive platform that connects 	 <u>montaji@dm.gov.ae</u>
Dubai Government and its customers:	 Dubai Municipality - Call Center (24/7):
The 04 Platform <u>https://04.gov.ae/</u>	800900
 Dubai Municipality - Call Center (24/7): 	
800900	

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13. Annex

In order to ensure the compliance of each product to the recommended limits by Dubai Municipality, products should be tested at Dubai Central Laboratory or any other accredited laboratory. The table below shows each category and its applicable test that can be performed.

Test Description	Specification limit				
General Safety Tests					
Cadmium 3ppm					
Toxic Metals (Cadmium, Lead, Chromium, Arsenic,	Lead 10ppm				
Mercury)	Arsenic 3 ppm				
	Mercury 3 ppm				
Note: as impurities / not added	Chromium (no standard)				
	*For baby products, oral care, eye care up to				
	1 ppm				
Asbestos	Absent - Not detected				
Zinc	1%				
Free Formaldehyde	Absent - Not detected				
	0.5% benzoic acid				
Preservatives (Benzoic Acid, Methyl 4- 0.4% Methyl Hydroxybenzoate (methylparaben					
Hydroxybenzoate, Ethyl 4-Hydroxybenzoate, n-Propyl	0.4% Ethyl Hydroxybenzoate (ethylparaben)				
4-Hydroxybenzoate and n-Butyl 4-xybenzoate)	0.4% Propyl Hydroxybenzoate (propylparaben)				
	0.4% Butyl Hydroxybenzoate (butylparaben)				
	0.8% Total Hydroxybenzoates				
Skin Whitening P	roducts				
Hydroquinone	Absent				
Hydrogen Peroxide	Skin products: 4%				
Hair and Scalp Pr	oducts				
1,4 Dioxane	10 ppm				
Hydrogen Peroxide	12 %				
	After mixing under oxidative conditions				
Oxidatives Colorants (p-Phenylenediamine and its salts)	the maximum concentration applied to hair must not				
	exceed 2 % calculated as free base				

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Oral Hygiene Products			
Total Fluoride	0.15%		
Di-ethylene Glycol	Absent		
	Oral products, including mouth rinse, toothpaste and tooth whitening or bleaching products: ≤ 0,1 %		
Hydrogen Peroxide	 *Specific for Tooth whitening or bleaching products: > 0,1 % ≤ 6 % *not allowed under 18 years *first use by dental practitioners 		
Lard in Cosmetics (Lips produ	icts, creams & soap)		
Analysis of Lard	Absent		
Perfumes , Toilet Waters, Eau de Cologne, cosmetic product			
Allergens Methanol	Allergens equal to or above the below limits should be indicated on the label (within the ingredients) as follow: - 0,001 % in leave-on products (e.g.: perfumes / lotion, cream) - 0,01 % in rinse-off products (e.g., shampoo, conditioner) Absent		
Microbiology			
Enumeration of Aerobic Mesophilic bacteria (Total bacterial count) Detection of Detection of Escherichia coli (E-Coli) Escherichia coli	< 1000 CFU/g Baby products: < 100 CFU/g All products: Absent		
Detection of Staphylococcus aureus	All products: Absent		
Detection of Pseudomonas aeruginosa	All products: Absent		
Detection of Candida albicans	All products: Absent		
Enumeration of Yeast & Mould	< 1000 CFU/g Baby products: < 100 CFU/g		

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*Notes:

- All the specification limit should be updated/revised as per the update in the regulation/standard.
- Cosmetic & personal care product may be subjected for further chemical testing as per the scope of

application to ensure safety / efficacy/ quality of all products placed in Dubai market.

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