

# **CHEMICAL RESTRICTIONS**

2016 edition

**BESTSELLER\***

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# INTRODUCTION

The BESTSELLER Chemical Restrictions (BCR) describes the limitation and prohibition of substances in products manufactured for BESTSELLER. The BCR have been developed based on the law, a concern for the health of our customers, the working conditions inside the factories producing our goods, and the preservation of the environment.

The listed values and additional notes in this document are applicable to all suppliers manufacturing or providing products for BESTSELLER.

The BCR apply to and cover all garments, accessories and other products of value (referred to as 'articles'). The articles include every type of supplement such as zippers, buttons, rivets and labels (list indicative not all-inclusive). Suppliers must also ensure that all samples meet the requirements set in the BCR. In addition, listed restrictions have been placed on the chemical content of all packaging and packaging additions used for storage, labelling and transportation of BESTSELLER articles which must be followed.

Suppliers must familiarise and comply with all legislation, product requirements and manufacturing requirements in all countries where they are producing. All environmental laws in the country of production must be followed. Production of articles for BESTSELLER must have minimal impact on the environment, and we expect suppliers to continuously work to reduce and control this impact.

Articles supplied by suppliers must meet legal requirements in all markets that BESTSELLER brands deliver to.

It is the responsibility of the supplier to ensure that articles they supply to BESTSELLER meet these requirements, which must be fully communicated to and controlled by all sub-contractors and suppliers of raw materials and components throughout the supply chain.

Suppliers should note that the BCR will be updated when necessary. Messages and updates regarding the BCR will be placed on the Supplier Portal news page.

# STRUCTURE

The BCR lists all substances which are not allowed or which are restricted in any product manufactured for or provided to BESTSELLER. These substances are set out in tables over the next few pages and should be studied in depth by all suppliers and communicated effectively to their production networks.

Chemical groups are listed in alphabetical order; individual chemicals are either listed in the table or placed in tables in the appendix.

**Substances that are not allowed to be used at any point during production are identified by the statement 'not allowed'** in the table, and are generally accompanied by a **'limit value'** – indicating the test result that determines whether this substance has been used or is present in the product.

The tables cover all product groups and product types – any additional notes on specific product groups can be found in notations or as additional information in the document.

# TABLES OF FORBIDDEN OR RESTRICTED SUBSTANCES

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT
<b>ALKYLPHENOL ETHOXYLATES (APEOs) and metabolites<sup>1</sup></b>		AFIRM Harmonized method / EN ISO 18254:2015	Not allowed
Nonylphenol ethoxylates NPEO	Various	TEXTILES: By Using Methanol extraction  PLASTIC AND RUBBER: By Using DCM extraction	Sum of NP, OP and NPEO OPEO = 100 ppm
Octylphenol ethoxylates OPEO	Various		
Nonylphenol (NP)	Various		Sum of NP and OP = 10 ppm
Octylphenol (OP)	Various		
<b>BIOLOGICALLY ACTIVE FINISHING PRODUCTS</b>		Declaration of non-use	Not allowed unless ingredient / treatment specifically approved by BESTSELLER
<b>CATIONIC AUXILIARIES</b>		Methanol extraction and analysis by LC-MS	10 ppm
Distearyl-dimethyl ammonium chloride (DSDMAC)	107-64-2		
di(tallow)dimethyl ammonium chloride (DTDMAC)	68783-78-8		
Di(hardened tallow) dimethyl ammonium chloride (DHTDMAC)	61789-80-8		
<b>CHLORINATED ORGANIC CARRIERS</b>		DIN 54232:2010	(Limit value total sum 1.0 ppm)
(Di-, Tri-, Tetra-, Penta-, Hexa-) Chlorinated Benzenes <sup>2</sup>	Various		
(Mono-, Di-, Tri-, Tetra-, Penta-) Chlorinated Toluenes <sup>3</sup>	Various		
<b>FLAME RETARDANTS<sup>4</sup></b>		In-house method; analysis with GC-MS or LC-MS	Not allowed (Limit value 5 ppm for each)
<b>FORMALDEHYDE</b>	50-00-0	Textile: EN ISO 14184-1:2011 AATCC 112 (for US)  LEATHER: ISO 17226:2008 or AATCC 112 (For US)	≤ 3 years: 16 ppm >3 years: 75 ppm

1 APEOs (NPEO and OPEO) / APs (NP and OP) must not be used at any stage in production of any material.  
2 See full list in appendix 1  
3 See full list in appendix 1  
4 Full list of not allowed flame retardants are listed in Appendix 1.

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT	
<b>ISOCYANATES<sup>5</sup></b>		ISO 10283 Extraction with a dried solvent, derivatization followed by LC/MS determination.	(Limit value 3 ppm for each)	
<b>ORGANOTIN COMPOUNDS</b>		CEN/ISO 16179:2012	1 ppm each	
Dibutyltin (DBT)	Various			
Diocetyl tin (DOT)	Various			
Monobutyltin (MBT)	Various		0.5 ppm each	
Tributyltin (TBT)	Various			
Triphenyltin (TPhT)	Various			
All tri-substituted Organotin compounds	Various			1 ppm each
<b>PERFLUORINATED CHEMICALS (PFCs)<sup>6</sup></b>		For FTOHs: Solvent extraction according to Draft CEN/TS 15968 and analysis by Gas Chromatograph Mass Spectrometer (GC-MS-MS)  For Others: Draft CEN/TS 15968 Solvent extraction and analysis by Liquid Chromatograph Tandem Mass Spectrometer (LC-MS-MS)	Not allowed	
1H,1H,2H,2H-Perfluoro-1-hexanol (4:2 FTOH)	2043-47-2		For FTOHs: 10 µg/m <sup>2</sup>	
1H,1H,2H,2H-Perfluoro-1-oktanol (6:2 FTOH)	647-42-7		For Others: 1 µg/m <sup>2</sup>	
1H,1H,2H,2H-Perfluoro-1-decanol (8:2 FTOH)	678-39-7			
1H,1H,2H,2H-Perfluoro-1-dodecanol (10:2 FTOH)	865-86-1			
Perfluorobutane Acid (PFBA)	375-22-4			
Perfluorotetradecanoic Acid (PFTeA)	376-06-7			
Perfluorohexane Acid (PFHxA)	307-24-4			
Perfluoroheptane Acid (PFHpA)	375-85-9			
Perfluorooctanoic Acid (PFOA)	335-67-1			
Perfluorononane Acid (PFNA)	375-95-1			
Perfluorodecane Acid (PFDA)	335-76-2			
Perfluorooctane Sulfonate (PFOS)	56773-42-3			
<b>PESTICIDES<sup>7</sup></b> (sum incl. PCP and TeCP) (For natural materials only)			Extraction with acetone, silica gel clean up, analysis with GC-MS	0.5 ppm each

5 Restricted isocyanates are listed in Appendix 1.  
6 Relevant for all materials with a water and oil repellent finish or coating. The use of PFC technology is not allowed.  
7 Not allowed pesticides, TeCPs and TrCPs are listed in Appendix 1.

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT
<b>PHENOLS</b>		KOH extraction,15 hours at 90 degrees C § 64 LFGB B 82.02-08 or DIN EN ISO 17070:2015	
<b>CHLORINATED PHENOLS</b>			
2,3,4-Trichlorophenol	15950-66-0		0.5 ppm
2,3,5-Trichloropheno	933-78-8		
2,3,6-Trichlorophenol	933-75-5		
2,4,5-Trichloropheno	95-95-4		
2,4,6-Trichlorophenol	88-06-2		
3,4,5-Trichloropheno	609-19-8		
2,3,4,5-Tetrachlorophenol (TeCP)	4901-51-3		
2,3,4,6-Tetrachlorophenol (TeCP)	58-90-2		
2,3,5,6-Tetrachlorophenol (TeCP)	935-95-5		
Pentachlorophenol (PCP)	87-86-5		
<b>OTHER PHENOLS</b>			
Orthophenylphenol (OPP)	90-43-7	Sample Preparation: §64 BVL B 82.02.08 Measurement: GC-MS, LC-MS for confirmation	1000 ppm
<b>pH VALUE<sup>8</sup></b>		Textiles and PU:BS EN ISO 3071 USA: AATCC 81	Garment: 4.0- 7.5 Footwear: 4.0 to 8.5 Children ≤ 3 Years : 4.0 -7.5
		Leather: ISO 4045 USA: ASTM D2810	Garment: 3.2-7.5 Footwear: 3.2 to 8.5 Children ≤ 3 Years : 3.2 -7.5
<b>PHthalATES<sup>9</sup></b>		ISO 14389 Footwear EN ISO/TS 16181 for USA CPSC-CH-C1001-09.3	Not allowed (Limit value 0.05% for each. Total content of all phthalates not to exceed 0.1%)
<b>POLYAMINO CARBOXYLIC ACIDS</b>			
Ethylene diaminetetraacetate (EDTA)	60-00-4	Declaration of non-use	Not allowed
Diethylene triaminepentaacetate (DTPA)	67-43-6		

<sup>8</sup> Test applicable for direct and prolonged skin contact

<sup>9</sup> Phthalates must not be used at any stage in production of any material. Applicable for coated articles, plastisol prints, flexible foams, and accessories and additions made from plastics. The individual phthalates are listed in Appendix 1.

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT	
<b>POLYCYCLIC AROMATIC HYDROCARBONS (PAHs)<sup>10</sup></b>		AfPS GS 2014:01 PAK		
Acenaphtene	83-32-9		No individual restriction	Total 10 ppm
Acenaphthylene	208-96-8			
Anthracene	120-12-7			
Benzo(g,h,i)perylene	191-24-2			
Fluorene	86-73-7			
Fluoranthene	206-44-0			
Indeno(1,2,3-cd)pyrene	193-39-5			
Naphthalene**	91-20-3			
Phenanthrene	85-01-8			
Pyrene	129-00-0			
Benzo(a)anthracene	56-55-3		1 ppm each	
Benzo(a)pyrene	50-32-8		≤3 year: 0.5 ppm each	
Benzo(b)fluoranthene	205-99-2			
Benzo(e)pyrene	192-97-2			
Benzo(j)fluoranthene	205-82-3			
Benzo(k)fluoranthene	207-08-9			
Chrysene	218-01-9			
Dibenzo(a,h)anthracene	53-70-3			
<b>POLYVINYL CHLORIDE (PVC), POLYVINYLIDENE CHLORIDE (PVDC)<sup>11</sup></b>	9002-85-1, 9002-86-2	Belstein Test – if positive then FTIR must be performed	Not allowed	
<b>SHORT CHAINED CHLORINATED PARAFFINS (SCCP, C10-C13)</b>	85535-84-8	DIN EN ISO 18219 (modified), ultrasound extraction with n-Hexane, 60 min, 60°C, GC-MS/NCI analysis	Not allowed (Limit value 100 ppm)	

<sup>10</sup> PAHs are generally found in rubber, soft plastic products, especially darker colours.

<sup>11</sup> PVC and PVDC must not be used at any stage in production of any materials.

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT
<b>SOLVENT RESIDUES/ VOLATILE ORGANIC COMPOUNDS (VOCs)</b>			
Dimethylformamide (DMFa)	68-12-2	Solvent extraction (methanol, 70°C, 1 h)	500 ppm
Benzene	71-43-2	Headspace GC-MS (1 g sample, 120°C, 45 min)	Not allowed (Limit value 1.0 ppm)
Toluene <sup>12</sup>	108-88-3		(no intentional use) (Limit value 100 ppm)
Others <sup>13</sup>			Limit value 10 ppm for each
<b>OTHER CHEMICALS</b>			
2(thiocyanatomethylthio)-1,3benzothiazole (TCMTB) <sup>14</sup>	21564-17-0	In-house method. Analysis using GC-MS	30 ppm

## TABLES OF FORBIDDEN OR RESTRICTED SUBSTANCES, COLOURANTS/DYES

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT
<b>AZODYES RELEASING CLEAVABLE ARYLMINES</b>		LFGB § 64 B82.02-2,-4,-15	(Limit value 20 ppm for each)
4-Aminobiphenyl	92-67-1	EN14362-1:2012, EN 14362-3:2012	
Benzidine	92-87-5		
4-Chloro-o-toluidine	95-69-2	Leather: LFGB § 64 B 82.02-3, -9 ISO 17234-1,-2	
2-Naphthylamine	91-59-8		
o-Aminoazotoluene	97-56-3		
2-Amino-4-nitrotoluene	99-55-8		
4-Chloroaniline (para-)	106-47-8		
2,4-Diaminoanisole	615-05-4		
4,4'-Diaminobiphenylmethane	101-77-9		
3,3'-Dichlorobenzidine	91-94-1		
3,3'-Dimethoxybenzidine	119-90-4		
3,3'-Dimethylbenzidine	119-93-7		
3,3'-Dimethyl-4,4'-diaminobiphenylmethane	838-88-0		
p-Cresidine	120-71-8		
4,4'-Methylene-bis-(2-chloroaniline)	101-14-4		
4,4'-Oxydianiline	101-80-4		
4,4'-Thiodianiline	139-65-1		
o-Toluidine	95-53-4		

<sup>12</sup> Toluene usage ban in products and glues/solvents/inks/primes etc.

<sup>13</sup> Other solvent residues / volatile organic compounds (VOCs) are listed in Appendix 1.

<sup>14</sup> TCMTB is a fungicide which has several uses. TCMTB is used in industrial/residential materials preservatives (mainly leather products and hides). This is a concern for leather products.

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT
2,4-Toluyldiamine	95-80-7	LFGB § 64 B82.02-2,-4,-15	Not allowed (Limit value 20 ppm for each)
2,4,5-Trimethylaniline	137-17-7	EN14362-1:2012, EN 14362-3:2012	
o-Anisidine (2-Methoxyaniline)	90-04-0	Leather: LFGB § 64 B 82.02-3, -9 ISO 17234-1,-2	
4-Aminoazobenzene	60-09-3		
2,4-Xylidine	95-68-1		
2,6-Xylidine	87-62-7		
<b>'Blue colourant'</b> Component 1: C <sub>12</sub> H <sub>10</sub> ClCrN <sub>2</sub> O <sub>2</sub> S <sub>2</sub> Na Component 2: C <sub>16</sub> H <sub>30</sub> CrN <sub>2</sub> S <sub>3</sub> Na	Not allocated CAS-No: 118685-33-9 Index no. 611-070-00-2	According to DIN 54231	Not allowed (Limit value 50 ppm)
<b>DYES AND PIGMENTS CLASSIFIED AS CARCINOGENIC</b>		DIN 54231	Not allowed (Limit value 75 ppm for each)
Acid red 26	3761-53-3		
Basic Blue 26	2580-56-5		
Basic Green 4	569-64-2		
	2437-29-8		
	10309-95-2		
Basic Red 9	569-61-9		
Basic Violet 3	548-62-9		
Basic Violet 14	632-99-5		
Direct Black 38	1937-37-7		
Direct Blue 6	2602-46-2		
Disperse Blue 1	2475-45-8		
Disperse Yellow 3	2832-40-8		
Direct Red 28	537-58-0		
Disperse Orange 11	82-28-0		
Pigment Red 104	12656-85-8		
Pigment Yellow 34	1344-37-2		

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT
<b>DYES CLASSIFIED AS ALLERGENIC</b>		DIN 54231	Not allowed (Limit value 75 ppm for each)
Disperse blue 1	1344-37-2		
Disperse Blue 3	2475-45-8		
Disperse Blue 7	3179-90-6		
Disperse Blue 26	3860-63-7		
Disperse Blue 35	12222-75-2		
Disperse Blue 102	12222-97-8		
Disperse Blue 106	12223-01-7		
Disperse Blue 124	61951-51-7		
Disperse Brown 1	23355-64-8		
Disperse Orange 1	2581-69-3		
Disperse Orange 3	730-40-5		
Disperse Orange 76/37/59	51811-42-8		
Disperse Red 1	2872-52-8		
Disperse Red 11	2872-48-2		
Disperse Red 17	3179-89-3		
Disperse Yellow 1	119-15-3		
Disperse Yellow 3	2832-40-8		
Disperse Yellow 9	6373-73-5		
Disperse Yellow 39	12236-29-2		
Disperse Yellow 49	54824-37-2		
<b>OTHER BANNED DYES</b>			
Disperse Orange 149	85136-74-9		
Disperse Yellow 23	6250-23-3		
<b>CHROME MORDANT</b>		Declaration of non-use	Not Allowed

# TABLES OF FORBIDDEN OR RESTRICTED SUBSTANCES: METALS

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT
<b>EXTRACTABLE HEAVY METALS</b>			
Antimony (Sb)	7440-36-0	Sample preparation: EN ISO 105-E04:2013 Measurement: EN ISO 17294-2:2014	30 ppm
Arsenic (As)	7440-38-2	Sample preparation: Extractable: Textiles: EN ISO 105-E04:2013 Leather: DIN EN ISO 17072-1:2014 Total: Microwave digestion with H <sub>2</sub> O <sub>2</sub> /HNO <sub>3</sub> Measurement: EN ISO 17294-2:2014	0.2 ppm
Cadmium (Cd)	7440-43-9	Sample preparation: Extractable: Textiles: EN ISO 105-E04:2013 Leather: DIN EN ISO 17072-1:2014 Total: Microwave digestion with H <sub>2</sub> O <sub>2</sub> /HNO <sub>3</sub> Measurement: EN ISO 17294-2:2014	0.1 ppm
Chromium (Cr)	7440-47-3	Sample preparation: EN ISO 105-E04:2013 Measurement: EN ISO 17294-2:2014	1.0 ppm Leather: 60 ppm
Chromium (VI)	18540-29-9	Sample preparation: Textile: EN ISO 105-E04:2013 Leather ageing: Conditions for leather ageing: 24 hours, 80 degrees C, maximum 5% relative humidity, no ventilation; EN 17075-1:2015 Measurement: Textile: EN ISO 17294-2 Leather: EN 17075-1:2015	Extractable: Adults: 3 ppm Children and babies (≤3 years): 0.5 ppm
Cobalt (Co)	7440-48-4	Sample preparation: EN ISO 105-E04:2013 Measurement: EN ISO 17294-2	1 ppm
Copper (Cu) <sup>15</sup>	7440-50-8	Sample preparation: EN ISO 105-E04:2013 Measurement: EN ISO 17294-2:2014	25 ppm
Lead (Pb) <sup>16</sup>	7439-92-1	Sample preparation: Extractable: EN ISO 105-E04:2013 Total: Microwave digestion with H <sub>2</sub> O <sub>2</sub> /HNO <sub>3</sub> Lead in paint and surface coating: CPSIA Section 101.16 CFR 1303 Measurement: EN ISO 17294-2:2014	≤ 3 years: 0.2 ppm > 3 years: 1.0 ppm

<sup>15</sup> No requirements for accessories made from inorganic materials.

<sup>16</sup> The use of lead and lead alloys is forbidden.

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT
Mercury (Hg)	7439-97-6	Sample preparation: Extractable: EN ISO 105-E04:2013 Total: Microwave digestion with H <sub>2</sub> O <sub>2</sub> /HNO <sub>3</sub> Measurement: EN ISO 17294-2:2014	0.02 ppm
Nickel (Ni)	7440-02-0	Sample preparation: Textile: EN ISO 105-E04:2013 Metal parts: EN 12472:2005+ A1:2009 Measurement: Textile: EN ISO 17294-2:2014 Metal parts: EN 1811:2015	1 ppm
Selenium (Se)	7782-49-2	Sample preparation: EN ISO 105-E04:2013 Measurement: EN ISO 17294-2:2014	500 ppm
<b>TOTAL HEAVY METALS<sup>17</sup></b>			
Arsenic (As)	7440-38-2	Sample preparation: Microwave digestion with H <sub>2</sub> O <sub>2</sub> /HNO <sub>3</sub> Measurement: EN ISO 17294-2:2014	100 ppm
Cadmium (Cd) <sup>18</sup>	7440-43-9	Sample preparation: Microwave digestion with H <sub>2</sub> O <sub>2</sub> /HNO <sub>3</sub> Measurement: EN ISO 17294-2:2014 USA; Preparation: CPSC-CH-E1001-08 Measurement: CPSC-CH-E1002-08.	≤ 3 years: 40 ppm >3 years: 75 ppm
Lead (Pb)	7439-92-1	Sample preparation: Microwave digestion with H <sub>2</sub> O <sub>2</sub> /HNO <sub>3</sub> Metal as substrate: CPSC-CH-E1001-08-3 Metal as Surface Coating: CPSC-CH-E1003-09-1 Plastic and Glass: CPSC-CH-E1002-08-3	90 ppm  (Accessories made from glass: 500ppm)
Mercury (Hg)	7439-97-6	Sample preparation: Microwave digestion with H <sub>2</sub> O <sub>2</sub> /HNO <sub>3</sub> Measurement: EN ISO 17294-2:2014	0.5 ppm
Nickel (Ni)	7440-02-0	Nickel release test Coated item: EN 12472/ EN 1811:2011, Non-coated item: EN 1811:2011	0.5 µg/cm <sup>2</sup> /week 0.2 µg/cm <sup>2</sup> /week <sup>19</sup>
Total Cr (VI) after oven aging- (Leather only)	18540-29-9	ISO 17075 Aging procedure: 24 h at 80 °C and <5% humidity	Not allowed (Limit value 3.0 ppm)

<sup>17</sup> Applicable to all non textile accessories and components - and spun dyed fibres and articles containing pigments.

<sup>18</sup> No requirement for >3 years accessories made from glass.

<sup>19</sup> Any jewellery that pierces skin.



## TABLES OF FORBIDDEN OR RESTRICTED SUBSTANCES: PACKAGING

SUBSTANCE	CAS NO.	TEST METHOD	MAX LEVEL ALLOWED IN FINAL PRODUCT
<b>COBALT DICHLORIDE</b>	7646-79-9	Acid digestion, analysis by ICP-AES and/or ICP-MS	Not allowed (Limit value 0.1%)
<b>DIMETHYL FUMERATE (DMFu)<sup>20</sup></b>	624-49-7	GC-MS	Not allowed (Limit value 0.1 ppm)
<b>POLYVINYL CHLORIDE (PVC) POLYVINYLIDENE CHLORIDE (PVDC)</b>	9002-86-2	FTIR Belstein Test	Not allowed
<b>TOTAL HEAVY METALS<sup>21</sup></b>			
Cadmium (Cd)	7440-43-9	Acid digestion, analysis by ICP-AES and/or ICP-MS	Sum of all 4 must be below 100 ppm
Chromium (VI)	18540-29-9		
Lead (Pb)	7439-92-1		
Mercury (Hg)	7439-97-6		

<sup>20</sup> Can be found in sachets in packaging to prevent mould during transport.

<sup>21</sup> From Directive 'Packaging and packaging waste 94/62/EC.

## COSMETICS COUNTRY OF DESTINATION: EU CREAM AND LOTIONS

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS																				
<b>Main Regulatory Requirements</b>																							
<b>Heavy metal contamination (Pb, Cd, Hg, As, Sb, Ni)</b>	Acid digestion of the sample followed by ICP analysis If necessary nickel migration according to EN 71 with sweat simulant of DIN 53160	German Federal Health Agency Guideline on Heavy metals impurities in Cosmetics Lead < 20ppm Arsenic< 5ppm Cadmium< 5ppm Mercury< 1ppm Antimony< 10ppm Extractable Nickel< 10ppm																					
<b>Phthalates (DEHP, DBP, BBP, DMEP, DiPP, DnPP, PiPP, DIBP, DIHP, DHNUP)</b>	GC-MSD analysis	1223/2009 (EC) Prohibited	When packed in soft plastic																				
<b>Free (and bonded) Formaldehyde content</b>	HPLC analysis after derivatisation with DNPH	1223/2009 (EC) Warning statement should be presented on the product label if the free formaldehyde content >0.05% Max. allowed content 0.2 %	For all finished products containing formaldehyde or substances which release formaldehyde																				
<b>Analysis of N-nitrosodialkanol-amine (NDELA)</b>	GC-MSD analysis	1223/2009 (EC) Prohibited (Limit: not detected)	For formulations containing secondary and/or tertiary amines or other substances forming nitrosamines																				
<b>Microbial contamination</b>	European Pharmacopoeia methods 2.6.12 & 2.6.13 Or ISO 18416 ISO 22717 ISO 22718 ISO 21149 ISO 16212 ISO 21150	<table border="1"> <thead> <tr> <th>Microbial</th> <th>Limit Values</th> </tr> </thead> <tbody> <tr> <td>Total Viable Count for aerobic mesophilic micro-organism</td> <td>≤10<sup>3</sup> cfu/g (Category 1)</td> </tr> <tr> <td>- Total Bacterial Count - Total Combined moulds &amp; Yeast Count</td> <td>≤10<sup>2</sup> cfu/g (Category 2)</td> </tr> <tr> <td>Bile tolerant Gram negative bacteria</td> <td>Absent/g</td> </tr> <tr> <td>Staphylococcus aureus</td> <td>Absent/g</td> </tr> <tr> <td>Pseudomonas aeruginosa</td> <td>Absent/g</td> </tr> <tr> <td>Salmonella species</td> <td>Absent/g</td> </tr> <tr> <td>Escherichia coli</td> <td>Absent/g</td> </tr> <tr> <td>Clostridia species</td> <td>Absent/g</td> </tr> <tr> <td>Candida albicans</td> <td>Absent/g</td> </tr> </tbody> </table>	Microbial	Limit Values	Total Viable Count for aerobic mesophilic micro-organism	≤10 <sup>3</sup> cfu/g (Category 1)	- Total Bacterial Count - Total Combined moulds & Yeast Count	≤10 <sup>2</sup> cfu/g (Category 2)	Bile tolerant Gram negative bacteria	Absent/g	Staphylococcus aureus	Absent/g	Pseudomonas aeruginosa	Absent/g	Salmonella species	Absent/g	Escherichia coli	Absent/g	Clostridia species	Absent/g	Candida albicans	Absent/g	Category 1: Other products  Category 2: Baby products or products used on eye-area or mucosa membranes
Microbial	Limit Values																						
Total Viable Count for aerobic mesophilic micro-organism	≤10 <sup>3</sup> cfu/g (Category 1)																						
- Total Bacterial Count - Total Combined moulds & Yeast Count	≤10 <sup>2</sup> cfu/g (Category 2)																						
Bile tolerant Gram negative bacteria	Absent/g																						
Staphylococcus aureus	Absent/g																						
Pseudomonas aeruginosa	Absent/g																						
Salmonella species	Absent/g																						
Escherichia coli	Absent/g																						
Clostridia species	Absent/g																						
Candida albicans	Absent/g																						

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Efficacy of antimicrobial preservation</b>	European Pharmacopoeia Methods 5.1.3 or ISO 11930: 2012	European Pharmacopoeia Methods 5.1.3 or ISO 11930: 2012	Not necessary for single use products or low risk products acc. to ISO 29621
<b>Tolerance Test</b>	Skin or Eye Irritation Test	Not irritating or sensitizing.	Necessary for all kind of products in longer contact with skin or mucosa/eyes. If there are any claims e.g. for "sensible skin" or "dermatologically tested" such a test is necessary
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	2013/2/EU ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials
<b>Ingredient and labelling</b>			
<b>Ingredient Review</b>	Review the full ingredient based on the regulatory requirement, against those prohibited and restricted listed in the regulations	1223/2009 (EC) The ingredients of cosmetic must be complied with Annexes II, III, IV, V, VI of regulation 1223/2009 (EC) & subsequent amendments	
<b>Package Label Review</b>	Package label based on the regulatory requirement	The product information on the label should be presented in indelible, easily legible and visible lettering and using corresponding local language (see *):  <ul style="list-style-type: none"> <li>- Name and Address of the responsible person</li> <li>- The country of origin if the products have been imported from outside EU</li> <li>- Net content* (necessary ≥ 5g or ml)</li> <li>- Date of min. durability* for products with a durability up to 30 months (hourglass symbol) or period after opening for products with a durability over 30 months (open jar symbol)</li> <li>- Warning statement* if necessary</li> <li>- Batch no.</li> <li>- Function of the product*</li> </ul> List of ingredients:  <ul style="list-style-type: none"> <li>- preceded by "Ingredients"</li> <li>- Labelling of perfume (PARFUM) and aromatic (AROMA) compositions</li> <li>- Labelling of allergenic fragrances (over 10 ppm (leave-on products) or 100 ppm (rinse-off products))</li> <li>- Descending order of weight (over 1%)</li> <li>- Labelling of nanomaterials if necessary</li> <li>- Labelling of colourants with CI number except hair dyes</li> <li>- Colourants, except hair dyes, may be written at the end of ingredients list</li> <li>- INCI naming of ingredients</li> </ul>	All parameter on inner container and outer packaging  <ul style="list-style-type: none"> <li>- exemption: the list of ingredients may only appear on the outer packaging</li> </ul>
<b>Physical characteristics</b>			
<b>Net Content</b>	Standard Measure	As Reported	
<b>Appearance and Odor</b>	Visual & Organoleptic	As Reported	

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>pH Value</b>	Water Extraction, followed by analysis using pH meter	As reported	
<b>Percent Solid</b>	Dry it at 105°C for 3 hours	As Reported	
<b>Dispenser Function (if applicable)</b>	Visual inspection actual use	Shall function as intended after 50 operations	
<b>Product Dossier</b>			
<b>Product Information File (PIF) (Dossier)</b>	Documentation of technical information on raw material, finished product etc. Assessment acc. to Art. 11 of 1223/2009 (EC)	The PIF shall contain the following documents:  <ul style="list-style-type: none"> <li>- A description of the cosmetic</li> <li>- The cosmetic product safety report acc. to Article 10 (1) and the corresponding data</li> <li>- A description of the method of manufacturing and a statement on compliance with good manufacturing practice acc. to ISO 22716;</li> <li>- Where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product</li> <li>- Data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries – or a statement about absence of animal tests</li> </ul>	A PIF has to be available for 10 years after the product was last brought on the market.
<b>Cosmetic Product Safety Report (CPSR)</b>	Safety Assessment acc. to Art. 10 of 1223/2009 (EC)	A CPSR has to be performed by a Safety Assessor. For details see Annex I of 1223/2009 (EC)	
<b>Notification at Cosmetic Product Notification Portal (CPNP)</b>	Notification Assessment acc. to Art. 13 of 1223/2009 (EC)	Information about responsible person, marketing and formulation of the product has to be notified.	Organisation has to be registered at ECAS and SAAS
<b>Chemical &amp; Physical Test on Container</b>			
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	2013/2/EU ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials
<b>Chemical Analysis</b>	Digestion followed by ICP-AES analysis; GC analysis; AfPS GS 2014:01 PAK;	REACH-Regulation:  <ul style="list-style-type: none"> <li>- Cadmium and Lead Content applicable to plastic</li> <li>- Organotin (Expressed as tin)</li> <li>- PAH</li> <li>- Dimethyl Fumarate (DMF)</li> <li>- Substances of very high concern (SVHCs) on the current candidate list</li> </ul> POP-Regulation: - Short Chain Chlorinated paraffin (SCCP) content	
<b>Chemical Analysis – Document Check</b>	Art. 17 & Annex I of 1223/2009 (EC)	The used materials of the direct container have to be suitable for use with cosmetic products. Declaration of compliance shall be submitted (e.g. acc. to (EC) 1935/2004)	
<b>Physical Testing</b>		Overall Dimension (Length x Width x Height) Workmanship Stability Test Leakage Test Drop Test	

# SOAP, SHAMPOO AND CONDITIONER

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Main Regulatory Requirements</b>			
<b>Heavy metal contamination (Pb, Cd, Hg, As, Sb, Ni)</b>	Acid digestion of the sample followed by ICP analysis; If necessary nickel migration according to EN 71 with sweat simulatant of DIN 53160	German Federal Health Agency Guideline on Heavy metals impurities in Cosmetics  Lead < 20ppm Arsenic< 5ppm Cadmium< 5ppm Mercury< 1ppm Antimony< 10ppm Extractable Nickel< 10ppm	
<b>Phthalates (DEHP, DBP, BBP, DMEP, DiPP, DnPP, PiPP, DIBP, DIHP, DHNUP)</b>	GC-MSD analysis	1223/2009 (EC) Prohibited	When packed in soft plastic
<b>Free (and Bonded) Formaldehyde content</b>	HPLC analysis after derivatisation with DNPH	1223/2009 (EC) Warning statement should be presented on the product label if the free formaldehyde content > 0.05%  Max. allowed content 0.2 %	For all finished products containing formaldehyde or substances which release formaldehyde
<b>Analysis of N-nitrosodialkanolamine (NDELA)</b>	GC-MSD analysis	1223/2009 (EC) Prohibited (Limit: not detected)	For formulations containing secondary and/or tertiary amines or other substances forming nitrosamines
<b>1,4- Dioxane</b>	GC-MS analysis	1223/2009 (EC) Prohibited - Presence of traces shall be allowed provided that such presence is technically unavoidable under GMP condition	Should be tested when ethoxylated ingredients are used – e.g. Polysorbate, Sodium Laureth Sulfate, PEG ..., Cetareth, Laureth

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS	
<b>Microbial contamination</b>	European Pharmacopoeia methods 2.6.12 & 2.6.13 Or ISO 18416 ISO 22717 ISO 22718 ISO 21149 ISO 16212 ISO 21150	Microbial	Category 1: Other products  Category 2: Baby products or products used on eye-area or mucosa membranes	
		Total Viable Count for aerobic mesophilic micro-organism		Limit Values ≤10 <sup>3</sup> cfu/g (Category 1)  ≤10 <sup>2</sup> cfu/g (Category 2)
		- Total Bacterial Count - Total Combined moulds & Yeast Count		
		Bile tolerant Gram negative bacteria		Absent/g
		Staphylococcus aureus		Absent/g
		Pseudomonas aeruginosa		Absent/g
		Salmonella species		Absent/g
		Escherichia coli		Absent/g
		Clostridia species	Absent/g	
		Candida albicans	Absent/g	
<b>Efficacy of antimicrobial preservation</b>	European Pharmacopoeia Methods 5.1.3 or ISO 11930: 2012	European Pharmacopoeia Methods 5.1.3 or ISO 11930: 2012	Not necessary for single use products or low risk products acc. to ISO 29621	
<b>Tolerance Test</b>	Skin or Eye Irritation Test	Not irritating or sensitizing.	Necessary for all kind of products in longer contact with skin or mucosa/eyes. If there are any claims e.g. for "sensible skin" or "dermatologically tested" such a test is necessary	
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	2013/2/EU ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials	
<b>Ingredient and labelling</b>				
<b>Ingredient Review</b>	Review the full ingredient based on the regulatory requirement, against those prohibited and restricted listed in the regulations	1223/2009 (EC) The ingredients of cosmetic must be complied with Annexes II, III, IV, V, VI of regulation 1223/2009 (EC) & subsequent amendments		

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Package Label Review</b>	Package label based on the regulatory requirement	<p>The product information on the label should be presented in indelible, easily legible and visible lettering and using corresponding local language (see *):</p> <ul style="list-style-type: none"> <li>- Name and Address of the responsible person</li> <li>- The country of origin if the products have been imported from outside EU</li> <li>- Net content* (necessary ≥ 5g or ml)</li> <li>- Date of min. durability* for products with a durability up to 30 months (hourglass symbol) or period after opening for products with a durability over 30 months (open jar symbol)</li> <li>- Warning statement* if necessary</li> <li>- Batch no.</li> <li>- Function of the product*</li> <li>- List of ingredients: <ul style="list-style-type: none"> <li>- preceded by "Ingredients"</li> <li>- Labelling of perfume (PARFUM) and aromatic (AROMA) compositions</li> <li>- Labelling of allergenic fragrances (over 10 ppm (leave-on products) or 100 ppm (rinse-off products))</li> <li>- Descending order of weight (over 1%)</li> <li>- Labelling of nanomaterials if necessary</li> <li>- Labelling of colourants with CI number except hair dyes</li> <li>- Colourants, except hair dyes, may be written at the end of ingredients list</li> <li>- INCI naming of ingredients</li> </ul> </li> </ul>	<p>All parameter on inner container and outer packaging</p> <ul style="list-style-type: none"> <li>- exemption: the list of ingredients may only appear on the outer packaging</li> </ul>
<b>Physical characteristics</b>			
<b>Net Content</b>	Standard Measure	As Reported	
<b>Appearance and Odor</b>	Visual & Organoleptic	As Reported	
<b>pH Value</b>	Water Extraction, followed by analysis using pH meter	As reported	
<b>Water Content (For Liquide Soap products, Shampoo and Conditioner)</b>	Karl Fisher	As Reported	
<b>Viscosity (For Liquide Products)</b>	Viscometer	As Reported	
<b>Ross Mile Foam Test (For Soap Products and Shampoo)</b>	ISO 696	As Reported	
<b>Dispenser Function (if applicable)</b>	Visual inspection actual use	Shall function as intended after 50 operations	
<b>Product Dossier</b>			

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Product Information File (PIF) (Dossier)</b>	Documentation of technical information on raw material, finished product etc. Assessment acc. to Art. 11 of 1223/2009 (EC)	<p>The PIF shall contain the following documents:</p> <ul style="list-style-type: none"> <li>- a description of the cosmetic</li> <li>- the cosmetic product safety report acc. to Article 10 (1) and the corresponding data</li> <li>- a description of the method of manufacturing and a statement on compliance with good manufacturing practice acc. to ISO 22716;</li> <li>- where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product</li> <li>- data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries – or a statement about absence of animal tests</li> </ul>	A PIF has to be available for 10 years after the product was last brought on the market.
<b>Cosmetic Product Safety Report (CPSR)</b>	Safety Assessment acc. to Art. 10 of 1223/2009 (EC)	A CPSR has to be performed by a Safety Assessor. For details see Annex I of 1223/2009 (EC)	
<b>Notification at Cosmetic Product Notification Portal (CPNP)</b>	Notification Assessment acc. to Art. 13 of 1223/2009 (EC)	Information about responsible person, marketing and formulation of the product has to be notified.	Organisation has to be registered at ECAS and SAAS
<b>Chemical &amp; Physical Test on Container</b>			
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	2013/2/EU ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials
<b>Chemical Analysis</b>	Digestion followed by ICP-AES analysis; GC analysis; AfPS GS 2014:01 PAK;	<p>REACH-Regulation:</p> <ul style="list-style-type: none"> <li>- Cadmium and Lead Content applicable to plastic</li> <li>- Organotin (Expressed as tin)</li> <li>- PAH</li> <li>- Dimethyl Fumarate (DMF)</li> <li>- Substances of very high concern (SVHCs) on the current candidate list</li> </ul> <p>POP-Regulation:</p> <ul style="list-style-type: none"> <li>- Short Chain Chlorinated paraffin (SCCP) content</li> </ul>	
<b>Chemical Analysis – Document Check</b>	Art. 17 & Annex I of 1223/2009 (EC)	The used materials of the direct container have to be suitable for use with cosmetic products. Declaration of compliance shall be submitted (e.g. acc. to (EC) 1935/2004)	
<b>Physical Testing</b>		Overall Dimension (Length x Width x Height) Workmanship Stability Test Leakage Test Drop Test	

# PERFUME, FRAGRANCE AND BODY SPRAY

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS	
<b>Main Regulatory Requirements</b>				
<b>Heavy metal contamination (Pb, Cd, Hg, As, Sb, Ni)</b>	Acid digestion of the sample followed by ICP analysis; If necessary nickel migration according to EN 71 with sweat simulant of DIN 53160	German Federal Health Agency Guideline on Heavy metals impurities in Cosmetics Lead < 20ppm Arsenic< 5ppm Cadmium< 5ppm Mercury< 1ppm Antimony< 10ppm Extractable Nickel< 10ppm		
<b>Phthalates (DEHP, DBP, BBP, DMEP, DiPP, DnPP, PiPP, DIBP, DIHP, DHNUP)</b>	GC-MSD analysis	1223/2009 (EC) Prohibited	When packed in soft plastic	
<b>Free (and bonded) Formaldehyde content</b>	HPLC analysis after derivatisation with DNPH	1223/2009 (EC) Warning statement should be presented on the product label if the free formaldehyde content > 0.05%  Max. allowed content 0.2 %	For all finished products containing formaldehyde or substances which release formaldehyde	
<b>Analysis of N-nitrosodialkanol-amine (NDELA)</b>	GC-MSD analysis	1223/2009 (EC) Prohibited (Limit: not detected)	For formulations containing secondary and/or tertiary amines or other substances forming nitrosamines	
<b>Microbial contamination</b>	European Pharmacopoeia methods 2.6.12 & 2.6.13 Or ISO 18416 ISO 22717 ISO 22718 ISO 21149 ISO 16212 ISO 21150	Microbial	Limit Values	Category 1: Other products
		Total Viable Count for aerobic mesophilic micro-organism	≤10 <sup>3</sup> cfu/g (Category 1)	Category 2: Baby products or products used on eye-area or mucosa membranes
		- Total Bacterial Count	≤10 <sup>2</sup> cfu/g (Category 2)	
		- Total Combined moulds & Yeast Count		
		Bile tolerant Gram negative bacteria	Absent/g	
		Staphylococcus aureus	Absent/g	
		Pseudomonas aeruginosa	Absent/g	
		Salmonella species	Absent/g	
Escherichia coli	Absent/g			
Clostridia species	Absent/g			
Candida albicans	Absent/g			

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Efficacy of antimicrobial preservation</b>	European Pharmacopoeia Methods 5.1.3 or ISO 11930: 2012	European Pharmacopoeia Methods 5.1.3 or ISO 11930: 2012	Not necessary for single use products or low risk products acc. to ISO 29621
<b>Tolerance Test</b>	Skin or Eye Irritation Test	Not irritating or sensitizing.	Necessary for all kind of products in longer contact with skin or mucosa/eyes. If there are any claims e.g. for "sensible skin" or "dermatologically tested" such a test is necessary
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	2013/2/EU ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials
<b>Ingredient and labelling</b>			
<b>Ingredient Review</b>	Review the full ingredient based on the regulatory requirement, against those prohibited and restricted listed in the regulations	1223/2009 (EC) The ingredients of cosmetic must be complied with Annexes II, III, IV, V, VI of regulation 1223/2009 (EC) & subsequent amendments	
<b>Package Label Review</b>	Package label based on the regulatory requirement	The product information on the label should be presented in indelible, easily legible and visible lettering and using corresponding local language (see *):  <ul style="list-style-type: none"> <li>- Name and Address of the responsible person</li> <li>- The country of origin if the products have been imported from outside EU</li> <li>- Net content* (necessary ≥ 5g or ml)</li> <li>- Date of min. durability* for products with a durability up to 30 months (hourglass symbol) or period after opening for products with a durability over 30 months (open jar symbol)</li> <li>- Warning statement* if necessary</li> <li>- Batch no.</li> <li>- Function of the product*</li> </ul> <ul style="list-style-type: none"> <li>- List of ingredients:</li> <li>- preceeded by "Ingredients"</li> <li>- Labelling of perfume (PARFUM) and aromatic (AROMA) compositions</li> <li>- Labelling of allergenic fragrances (over 10 ppm (leave-on products) or 100 ppm (rinse-off products))</li> <li>- Descending order of weight (over 1%)</li> <li>- Labelling of nanomaterials if necessary</li> <li>- Labelling of colourants with CI number except hair dyes</li> <li>- Colourants, except hair dyes, may be written at the end of ingredients list</li> <li>- INCI naming of ingredients</li> </ul>	All parameter on inner container and outer packaging  <ul style="list-style-type: none"> <li>- exemption: the list of ingredients may only appear on the outer packaging</li> </ul>

# NAIL POLISH, NAIL STRENGTHENER, POLISH REMOVER

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Physical characteristics</b>			
<b>Net Content</b>	Standard Measure	As Reported	
<b>Appearance and Odor</b>	Visual & Organoleptic	As Reported	
<b>Flash Point</b>	ISO 3679	Closed cup/Rapid equilibrium	
<b>pH Value</b>	Water Extraction, followed by analysis using pH meter	As reported	
<b>Product Dossier</b>			
<b>Product Information File (PIF) (Dossier)</b>	Documentation of technical information on raw material, finished product etc. Assessment acc. to Art. 11 of 1223/2009 (EC)	The PIF shall contain the following documents: - a description of the cosmetic - the cosmetic product safety report acc. to Article 10 (1) and the corresponding data - a description of the method of manufacturing and a statement on compliance with good manufacturing practice acc. to ISO 22716; - where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product - data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries – or a statement about absence of animal tests	A PIF has to be available for 10 years after the product was last brought on the market.
<b>Cosmetic Product Safety Report (CPSR)</b>	Safety Assessment acc. to Art. 10 of 1223/2009 (EC)	A CPSR has to be performed by a Safety Assessor. For details see Annex I of 1223/2009 (EC)	
<b>Noticifation at Cosmetic Product Notification Portal (CPNP)</b>	Notification Assessment acc. to Art. 13 of 1223/2009 (EC)	Information about responsible person, marketing and formulation of the product has to be notified.	Organisation has to be registered at ECAS and SAAS
<b>Chemical &amp; Physical Test on Container</b>			
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	2013/2/EU ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials
<b>Chemical Analysis</b>	Digestion followed by ICP-AES analysis; GC analysis; AFPS GS 2014:01 PAK;	REACH-Regulation: - Cadmium and Lead Content applicable to plastic - Organotin (Expressed as tin) - PAH - Dimethyl Fumarate (DMF) - Substances of very high concern (SVHCs) on the current candidate list  POP-Regulation: - Short Chain Chlorinated paraffin (SCCP) content	
<b>Chemical Analysis – Document Check</b>	Art. 17 & Annex I of 1223/2009 (EC)	The used materials of the direct container have to be suitable for use with cosmetic products. Declaration of compliance shall be submitted (e.g. acc. to (EC) 1935/2004)	
<b>Physical Testing</b>		Overall Dimension (Length x Width x Height) Workmanship Stability Test Leakage Test Drop Test	

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Main Regulatory Requirements</b>			
<b>Heavy metal contamination (Pb, Cd, Hg, As, Sb, Ni)</b>	Acid digestion of the sample followed by ICP analysis; If necessary nickel migration according to EN 71 with sweat simulant of DIN 53160	German Federal Health Agency Guideline on Heavy metals impurities in Cosmetics Lead < 20ppm Arsenic< 5ppm Cadmium< 5ppm Mercury< 1ppm Antimony< 10ppm Extractable Nickel< 10ppm	
<b>Phthalates (DEHP, DBP, BBP, DMEP, DiPP, DnPP, PiPP, DIBP, DIHP, DHNUP)</b>	GC-MSD analysis	1223/2009 (EC) Prohibited	When packed in soft plastic
<b>Free (and bonded) Formaldehyde content</b>	HPLC analysis after derivatisation with DNPH	1223/2009 (EC) Warning statement should be presented on the product label if the free formaldehyde content > 0.05%  Max. allowed content 0.2 %	For all finished products containing formaldehyde or substances which release formaldehyde
<b>Analysis of N-nitrosodialkanol-amine (NDELA)</b>	GC-MSD analysis	1223/2009 (EC) Prohibited (Limit: not detected)	For formulations containing secondary and/or tertiary amines or other substances forming nitrosamines
<b>Microbial contamination</b>	European Pharmacopoeia methods 2.6.12 & 2.6.13 Or ISO 18416 ISO 22717 ISO 22718 ISO 21149 ISO 16212 ISO 21150	With reference to the SCCS's notes of Guidance for the Testing of Cosmetic Ingredients and their safety evaluation by The Scientific Committee on Consumer Safety, SCCS and European Pharmacopoeia	Category 1: Other products  Category 2: Baby products or products used on eye-area or mucosa membranes
		Microbial	Limit Values
		Total Viable Count for aerobic mesophyllic micro-organism	≤10 <sup>3</sup> cfu/g (Category 1) ≤10 <sup>2</sup> cfu/g (Category 2)
		- Total Bacterial Count - Total Combined moulds & Yeast Count	
		Staphylococcus aureus	Absent/g
		Pseudomonas aeruginosa	Absent/g
		Candida albicans	Absent/g
<b>Efficacy of antimicrobial preservation</b>	European Pharmacopoeia Methods 5.1.3 or ISO 11930: 2012	European Pharmacopoeia Methods 5.1.3 or ISO 11930: 2012	Not necessary for single use products or low risk products acc. to ISO 29621

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Methyl Methacrylate</b>	HPLC coupled with Pulsed Amperometric Detector	BfR (German Federal Institute for Risk Assessment) in its Opinion No. 014/2012 of 22 Dec. 2011 classifies concentrations of 80-90% methyl methacrylate in nail art substances as hazardous to health	For artificial nails on acrylic powder base
<b>Screening for (volatile) substances of Annex II and III</b>	GC analysis	Impurities coming from solvents e.g. Chloroalkyles, Isophoron, Naphthalene, Benzene, Hexane, Toluene	
<b>Tolerance Test</b>	Skin or Eye Irritation Test	Not irritating or sensitizing.	Necessary for all kind of products in longer contact with skin or mucosa/eyes. If there are any claims e.g. for "sensible skin" or "dermatologically tested" such a test is necessary
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	2013/2/EU ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials
<b>Ingredient and labelling</b>			
<b>Ingredient Review</b>	Review the full ingredient based on the regulatory requirement, against those prohibited and restricted listed in the regulations	1223/2009 (EC) The ingredients of cosmetic must be complied with Annexes II, III, IV, V, VI of regulation 1223/2009 (EC) & subsequent amendments	
<b>Package Label Review</b>	Package label based on the regulatory requirement	The product information on the label should be presented in indelible, easily legible and visible lettering and using corresponding local language (see *):  <ul style="list-style-type: none"> <li>- Name and Address of the responsible person</li> <li>- The country of origin if the products have been imported from outside EU</li> <li>- Net content* (necessary ≥ 5g or ml)</li> <li>- Date of min. durability* for products with a durability up to 30 months (hourglass symbol) or period after opening for products with a durability over 30 months (open jar symbol)</li> <li>- Warning statement* if necessary</li> <li>- Batch no.</li> <li>- Function of the product*</li> </ul> <ul style="list-style-type: none"> <li>- List of ingredients:</li> <li>- preceded by "Ingredients"- Labelling of perfume (PARFUM) and aromatic (AROMA) compositions</li> <li>- Labelling of allergenic fragrances (over 10 ppm (leave-on products) or 100 ppm (rinse-off products))</li> <li>- Descending order of weight (over 1%)</li> <li>- Labelling of nanomaterials if necessary</li> <li>- Labelling of colourants with CI number except hair dyes</li> <li>- Colourants, except hair dyes, may be written at the end of ingredients list</li> <li>- INCI naming of ingredients</li> </ul>	All parameter on inner container and outer packaging - exemption: the list of ingredients may only appear on the outer packaging

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Physical characteristics</b>			
<b>Net Content</b>	Standard Measure	As Reported	
<b>Appearance and Odor</b>	Visual & Organoleptic	As Reported	
<b>pH Value</b>	Water Extraction, followed by analysis using pH meter	As reported	
<b>Product Dossier</b>			
<b>Product Information File (PIF) (Dossier)</b>	Documentation of technical information on raw material, finished product etc. Assessment acc. to Art. 11 of 1223/2009 (EC)	The PIF shall contain the following documents:  <ul style="list-style-type: none"> <li>- a description of the cosmetic</li> <li>- the cosmetic product safety report acc. to Article 10 (l) and the corresponding data</li> <li>- a description of the method of manufacturing and a statement on compliance with good manufacturing practice acc. to ISO 22716;</li> <li>- where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product</li> <li>- data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries – or a statement about absence of animal tests</li> </ul>	A PIF has to be available for 10 years after the product was last brought on the market.
<b>Cosmetic Product Safety Report (CPSR)</b>	Safety Assessment acc. to Art. 10 of 1223/2009 (EC)	A CPSR has to be performed by a Safety Assessor. For details see Annex I of 1223/2009 (EC)	
<b>Notification at Cosmetic Product Notification Portal (CPNP)</b>	Notification Assessment acc. to Art. 13 of 1223/2009 (EC)	Information about responsible person, marketing and formulation of the product has to be notified.	Organisation has to be registered at ECAS and SAAS
<b>Chemical &amp; Physical Test on Container</b>			
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	2013/2/EU ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials
<b>Chemical Analysis</b>	Digestion followed by ICP-AES analysis; GC analysis; AfPS GS 2014:01 PAK;	REACH-Regulation: <ul style="list-style-type: none"> <li>- Cadmium and Lead Content applicable to plastic</li> <li>- Organotin (Expressed as tin)</li> <li>- PAH</li> <li>- Dimethyl Fumarate (DMF)</li> <li>- Substances of very high concern (SVHCs) on the current candidate list</li> </ul> POP-Regulation: <ul style="list-style-type: none"> <li>- Short Chain Chlorinated paraffin (SCCP) content</li> </ul>	
<b>Chemical Analysis – Document Check</b>	Art. 17 & Annex I of 1223/2009 (EC)	The used materials of the direct container have to be suitable for use with cosmetic products. Declaration of compliance shall be submitted (e.g. acc. to (EC) 1935/2004)	
<b>Physical Testing</b>		Overall Dimension (Length x Width x Height) Workmanship Stability Test Leakage Test Drop Test	

## COUNTRY OF DESTINATION: US & CANADA

\* Please note that the information in the below sections do not include Over-the-Counter Drug or Cosmetic/Drug requirements that fall under the U.S. regulations. In the U.S. sunscreens and other products that may affect the structure or function of the skin (e.g. acne treatments, anti-aging, or skin protection products, etc.) may be considered a drug or cosmetic/drug based on the claims and ingredients.

\*\* Please note that the information in the below sections do not include Drug or Natural Health Product (NHP) requirements that fall under the Canadian regulations. In Canada, sunscreen products and some skin protection products may be considered a drug or NHP depending on the claims and the ingredients.

## CREAM AND LOTIONS

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS										
<b>Main Regulatory Requirements</b>													
<b>Heavy metal contamination (Pb, Cd, Hg, As, Sb)</b>	Acid digestion of the sample followed by ICP analysis	<b>US</b> 21 CFR 700.13. US FDA  Mercury: Less than 1 ppm for general cosmetics Mercury: Less than 65 ppm for cosmetics intended to be used on the eye area  CA Prop 65 Country of Alameda Court case No. H217587 (consolidated with 01-032306)  ≤0.35 ppm lead content ( Lip/mouth products) ≤0.5 ppm lead content (All other Cosmetics)											
		<b>Canada</b>  Health Canada Guidance on Heavy Metal Impurities in Cosmetics  Lead < 10ppm Arsenic < 3ppm Cadmium < 3ppm Mercury< 3ppm Antimony< 5ppm											
<b>Microbial contamination</b>	USP <61>	<b>US</b>	# The Personal Care Products Council ( PCPC) guideline limit										
		<table border="1"> <tr> <td>Product Type</td> <td>Total Plate Count + Yeast &amp; Mold Limit Values</td> </tr> <tr> <td>Baby products</td> <td>NMT 500 CFU per g or mL</td> </tr> <tr> <td>Eye area products</td> <td>NMT 500 CFU per g or mL</td> </tr> <tr> <td>All other Products</td> <td>NMT 5,000 CFR per g or mL</td> </tr> </table>		Product Type	Total Plate Count + Yeast & Mold Limit Values	Baby products	NMT 500 CFU per g or mL	Eye area products	NMT 500 CFU per g or mL	All other Products	NMT 5,000 CFR per g or mL		
		Product Type		Total Plate Count + Yeast & Mold Limit Values									
		Baby products		NMT 500 CFU per g or mL									
Eye area products	NMT 500 CFU per g or mL												
All other Products	NMT 5,000 CFR per g or mL												
<table border="1"> <tr> <td>Product Type</td> <td>TPC</td> </tr> <tr> <td>Children &amp; Infants</td> <td>LT 100 CFU / mL or g</td> </tr> <tr> <td>Mouth, Nose, Eyes, Genitalia Or aerosol products</td> <td>LT 100 CFU / mL or g</td> </tr> <tr> <td>Other Products</td> <td>LT 1,000 CFU / mL or g</td> </tr> <tr> <td>Product Type</td> <td>TPC</td> </tr> </table>	Product Type	TPC	Children & Infants	LT 100 CFU / mL or g	Mouth, Nose, Eyes, Genitalia Or aerosol products	LT 100 CFU / mL or g	Other Products	LT 1,000 CFU / mL or g	Product Type	TPC			
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Children & Infants	LT 100 CFU / mL or g												
Mouth, Nose, Eyes, Genitalia Or aerosol products	LT 100 CFU / mL or g												
Other Products	LT 1,000 CFU / mL or g												
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Product Type	TPC												
<b>Microbial contamination</b>	USP <61>	<b>CANADA</b>	Health Canada acceptance criteria										
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		Product Type		TPC									
		Children & Infants		LT 100 CFU / mL or g									
		Mouth, Nose, Eyes, Genitalia Or aerosol products		LT 100 CFU / mL or g									
Other Products	LT 1,000 CFU / mL or g												
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TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS		
<b>Microbial contamination</b>	USP <62>	<b>US</b>	# The Personal Care Products Council ( PCPC) guideline limit		
		Microbial		Limit Values	
		Escherichia coli		None detected	
		Staphylococcus aureus		None detected	
		Pseudomonas aeruginosa		None detected	
<b>Microbial contamination</b>	USP <62>	Canada  Candida albicans, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus shall be absent from all cosmetic product types	Health Canada acceptance criteria		
<b>Efficacy of antimicrobial preservation</b>	PCPC Preservative Effectiveness	<b>US &amp; Canada</b>			
		Day	Bacteria	Fungi	
		7	≥ 99.9%	≥ 90%	
		14	≥ 99.9%	≥ 90%	
		28	≥ 99.9%	≥ 90%	
		<b>Eye (aqueous)</b>			
		Day	Bacteria	Spore forming bacteria	Fungi
		7	≥ 99.9%	NI	≥ 90%
		14	Continued reduction	NI	Continued reduction
		28	None detected	NI	Continued reduction
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	<b>US</b>  Toxics in Packaging law (Toxics in Packaging Clearinghouse)  California, Connecticut, Florida, Georgia, Illinois, Iowa, Maine, Maryland, Minnesota, Missouri, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, Wisconsin)  ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials		
<b>Ingredient and labelling</b>					
<b>Toxicological risk assessment (TRA) on the formulation</b>	Review the hazard, exposure and risk on the full ingredient and evaluate the safety of the product by a Toxicologist	<b>US</b> FD&C Act Take reference to the definition of 16 CFR 1500.3  <b>Canada</b> Cosmetic Regulation of the Food and Drug Act; C.R.C., c.869 and Hotlist (List of prohibited and Restricted Cosmetics Ingredients)  Review the hazard, exposure and risk on the full ingredient and evaluate the safety of the product by a Toxicologist	Alternate hazard assessment tests may be deemed acceptable by the FDA or Health Canada for determining the safety of a product (e.g. in-vivo or in-vitro testing)		

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Ingredient Review</b>	Review the full ingredient based on the regulatory requirement, against those prohibited and restricted listed in the regulations	<b>US</b> US FDA, Food Drug and Cosmetics Regulations (21 CFR 73, 74, 81, 82, 250 & 700 to 740)  <b>Canada</b> Sections 17-24 of Cosmetic Regulation of the Food and Drug Act; C.R.C, c.869 and Hotlist (List of Prohibited and Restricted Cosmetic Ingredients)	
<b>Package Label Review</b>	Package label based on the regulatory requirement	<b>US</b> Federal Food, Drug, and Cosmetic Act (FFDCA or FDCA), 21 CFR 701 & 740, Fair Packaging and Labeling Act  <b>Canada</b> Canada Food and Drug Act, Cosmetic Regulation, the Consumer Packaging and Labelling Act and Regulations	
<b>Country of Origin Marking</b>	19 CFR 134.11	<b>US</b> Shall indicate country of Origin legibly and permanently and in a conspicuous place. It must also be in a close proximity and in comparable size to the name of country or locality other than the country of origin appears on the marking. Must be visible at point of purchase.	
<b>Physical characteristics</b>			
<b>Net Content</b>	Standard Measure	As Reported	
<b>Appearance and Odor</b>	Visual & Organoleptic	As Reported	
<b>pH Value</b>	Water Extraction, followed by analysis using pH meter	As reported	<BSch: When we measure pH, we normally perform it as-is for creams/ lotions – we don't perform a water extraction. If they wish for us to prepare the sample prior to measuring pH, we need instructions on how they wish us to do so>
<b>Physical Test on Container</b>			
<b>Physical Testing</b>		Overall Dimension (Length x Width x Height)  Workmanship Stability Test Leakage Test Drop Test	

# SOAP, SHAMPOO AND CONDITIONER

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Main Regulatory Requirements</b>			
<b>Heavy metal contamination (Pb, Cd, Hg, As, Sb)</b>	Acid digestion of the sample followed by ICP analysis	<p><b>US</b> 21 CFR 700.13. US FDA</p> <p>Mercury: Less than 1 ppm for general cosmetics</p> <p>Mercury: Less than 65 ppm for cosmetics intended to be used on the eye area</p> <p>CA Prop 65 Country of Alameda Court case No. H217587 (consolidated with 01-032306)</p> <p>≤0.5 ppm lead content Canada</p> <p>Health Canada Guidance on Heavy Metal Impurities in Cosmetics</p> <p>Lead &lt; 10ppm Arsenic &lt; 3ppm Cadmium &lt; 3ppm Mercury&lt; 3ppm Antimony&lt; 5ppm</p>	
<b>1,4 Dioxane</b>	Headspace GC-MS analysis	<p><b>US</b> CA Prop 65 Alameda County Superior Court Case No. RG 08-389960</p> <p>County of San Francisco Court Case No. CGG 10 500758</p> <p>≤10 ppm 1,4-Dioxane otherwise warning label required ( Soap Products and Shampoo)</p> <p><b>Canada</b> Hotlist ( List of prohibited and Restricted Cosmetic Ingredients)</p> <p>Prohibited</p> <p>#Presence of trace shall be allowed provided that such presence is technically unavoidable under GMP condition</p>	

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS		
<b>Cocamide DEA</b>	HPLC-MS analysis	<p>CA Prop 65 Country of Alameda Case No. RG 13-698427</p> <p>Product containing cocamide DEA (cocamide diethanolamine/cocamide diethanolamine condensate) shall not be manufactured, distributed, solid or offered for sale provided that cocamide DEA is an intentionally added ingredient in the product and/or part of the product formulation.</p>			
<b>Efficacy of antimicrobial preservation</b>	USP < 51> or ISO 11930: 2012	USP < 51> or ISO 11930: 2012			
<b>Microbial contamination</b>	USP <61>	<b>US</b>	# The Personal Care Products Council (PCPC) guideline limit		
		Product Type		Total Plate Count + Yeast & Mold Limit Values	
		Baby products		NMT 500 CFU per g or mL	
		All other Products	NMT 5,000 CFU per g or mL		
<b>Microbial contamination</b>	USP <61>	<b>Canada</b>	Health Canada acceptance criteria		
		Product Type		TPC	Y&M
		Children & Infants		LT 100 CFU / mL or g	LT 10 CFU / mL or g
		Other Products		LT 1,000 CFU / mL or g	LT 100 CFU / mL or g
<b>Microbial contamination</b>	USP <62>	<b>US</b>	# The Personal Care Products Council ( PCPC) guideline limit		
		Microbial		Limit Values	
		Escherichia coli		None detected	
		Staphylococcus aureus		None detected	
		Pseudomonas aeruginosa	None detected		
<b>Microbial contamination</b>	USP <62>	<b>Canada</b> Candida albicans, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus shall be absent from all cosmetic product types	Health Canada acceptance criteria		
<b>Efficacy of antimicrobial preservation</b>	PCPC Preservative Effectiveness	<b>US &amp; Canada</b>			
		Day		Bacteria	Fungi
		7		≥ 99.9%	≥ 90%
		14		≥ 99.9%	≥ 90%
		28		≥ 99.9%	≥ 90%

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	<b>US</b> Toxics in Packaging law (Toxics in Packaging Clearinghouse) California, Connecticut, Florida, Georgia, Illinois, Iowa, Maine, Maryland, Minnesota, Missouri, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, Wisconsin) ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials
<b>Ingredient and labelling</b>			
<b>Toxicological risk assessment (TRA) on the formulation</b>	Review the hazard, exposure and risk on the full ingredient and evaluate the safety of the product by a Toxicologist	<b>US</b> FD&C Act Take reference to the definition of 16 CFR 1500.3  Canada Cosmetic Regulation of the Food and Drug Act; C.R.C., c.869 and Hotlist (List of prohibited and Restricted Cosmetics Ingredients)  Review the hazard, exposure and risk on the full ingredient and evaluate the safety of the product by a Toxicologist	Alternate hazard assessment tests may be deemed acceptable by the FDA or Health Canada for determining the safety of a product (e.g. in-vivo or in-vitro testing)
<b>Ingredient Review</b>	Review the full ingredient based on the regulatory requirement, against those prohibited and restricted listed in the regulations	<b>US</b> US FDA, Food Drug and Cosmetics Regulations (21 CFR 73, 74, 81, 82, 250 & 700 to 740  Canada Sections 17-24 of Cosmetic Regulation of the Food and Drug Act; C.R.C. c.869 and Hotlist (List of Prohibited and Restricted Cosmetic Ingredients)	
<b>Package Label Review</b>	Package label based on the regulatory requirement	<b>US</b> Federal Food, Drug, and Cosmetic Act (FFDCA or FDCA), 21 CFR 701 & 740, Fair Packaging and Labeling Act  Canada: Canada Food and Drug Act, Cosmetic Regulation, the Consumer Packaging and Labelling Act and Regulations	
<b>Country of Origin Marking</b>	19 CFR 134.11	<b>US</b> Shall indicate country of Origin legibly and permanently and in a conspicuous place. It must also be in a close proximity and in comparable size to the name of country or locality other than the country of origin appears on the marking. Must be visible at point of purchase.	
<b>Physical characteristics</b>			
<b>Net Content</b>	Standard Measure	As Reported	
<b>Appearance and Odor</b>	Visual & Organoleptic	As Reported	

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>pH Value</b>	Water Extraction, followed by analysis using pH meter	As reported	<BSch: When we measure pH, we normally perform it as-is for creams/ lotions – we don't perform a water extraction. If they wish for us to prepare the sample prior to measuring pH, we need instructions on how they wish us to do
<b>Water Content (For Liquid Soap Products, Shampoo and Conditioner)</b>	Karl Fisher	As reported	
<b>Viscosity (For Liquid Product)</b>	Viscometer	As reported	
<b>Ross Mile Foam Test (For Soap Products and Shampoo)</b>	ISO 696	As reported	
<b>Dispenser Function (If applicable)</b>	Visual Inspection actual use	Shall function as intended after 50 operations	
<b>Physical Test on Container</b>			
<b>Physical Testing</b>		Overall Dimension (Length x Width x Height) Workmanship Stability Test Leakage Test Drop Test	

# PERFUME, FRAGRANCE AND BODY SPRAY

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Main Regulatory Requirements</b>			
<b>Heavy metal contamination (Pb, Cd, Hg, As, Sb)</b>	Acid digestion of the sample followed by ICP analysis	<b>US</b> 21 CFR 700.13. US FDA  Mercury: Less than 1 ppm for general cosmetics Mercury: Less than 65 ppm for cosmetics intended to be used on the eye area  CA Prop 65 Country of Alameda Court case No. H217587 (consolidated with 01-032306)  ≤0.5 ppm lead content	
		<b>Canada</b> Health Canada Guidance on Heavy Metal Impurities in Cosmetics  Lead < 10ppm Arsenic < 3ppm Cadmium < 3ppm Mercury < 3ppm Antimony < 5ppm	
<b>Total Volatile Organic Compound Content (VOC)</b>	California Air Resources Board (CARB) Method 310	California Code of Regulations Title 17, Division 3, chapter 1, Air Resources Board. Subchapter 8.5, Consumer Products. Article 2, Consumer Products-§94509  Products with 20% or less fragrance: <75%  Products with more than 20% fragrance: <65%	
<b>Microbial contamination</b>	USP <61>	<b>US</b>  Product Type                      Total Plate Count + Yeast & Mold Limit Values  All other Products                      NMT 5,000 CFR per g or mL	
		<b>Canada</b>  Product Type    TPC                      Y&M  Other Products    LT 1,000 CFU / mL or g                      LT 100 CFU / mL or g	

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS	
<b>Microbial contamination</b>	USP <62>	<b>US</b>  Microbial                      Limit Values  Escherichia coli                      None detected  Staphylococcus aureus                      None detected  Pseudomonas aeruginosa                      None detected		
		<b>Canada</b>  Candida albicans, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus shall be absent from all cosmetic product types		Health Canada acceptance criteria
		<b>US &amp; Canada</b>  Day                      Bacteria                      Fungi  7                      ≥ 99.9%                      ≥ 90%  14                      ≥ 99.9%                      ≥ 90%  28                      ≥ 99.9%                      ≥ 90%		
		<b>Lead, Cadmium, Mercury and Chromium (VI)</b>  Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy		<b>US</b>  Toxics in Packaging law (Toxics in Packaging Clearinghouse)  California, Connecticut, Florida, Georgia, Illinois, Iowa, Maine, Maryland, Minnesota, Missouri, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, Wisconsin)  ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))
<b>Ingredient and labelling</b>				
<b>Toxicological risk assessment (TRA) on the formulation</b>	Review the hazard, exposure and risk on the full ingredient and evaluate the safety of the product by a Toxicologist	<b>US</b> FD&C Act Take reference to the definition of 16 CFR 1500.3  <b>Canada</b> Cosmetic Regulation of the Food and Drug Act; C.R.C., c.869 and Hotlist (List of prohibited and Restricted Cosmetics Ingredients)  Review the hazard, exposure and risk on the full ingredient and evaluate the safety of the product by a Toxicologist	Alternate hazard assessment tests may be deemed acceptable by the FDA or Health Canada for determining the safety of a product (e.g. in-vivo or in-vitro testing)	
<b>Ingredient Review</b>	Review the full ingredient based on the regulatory requirement, against those prohibited and restricted listed in the regulations	<b>US</b> US FDA, Food Drug and Cosmetics Regulations (21 CFR 73, 74, 81, 82, 250 & 700 to 740)  <b>Canada</b> Sections 17-24 of Cosmetic Regulation of the Food and Drug Act; C.R.C. c.869 and Hotlist (List of Prohibited and Restricted Cosmetic Ingredients)		

# NAIL POLISH, NAIL STRENGTHENER, POLISH REMOVER

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Package Label Review</b>	Package label based on the regulatory requirement	<b>US</b> Federal Food, Drug, and Cosmetic Act (FFDCA or FDCA), 21 CFR 701 & 740, Fair Packaging and Labeling Act  <b>Canada</b> Canada Food and Drug Act, Cosmetic Regulation, the Consumer Packaging and Labelling Act and Regulations	
<b>Country of Origin Marking</b>	19 CFR 134.11	<b>US</b> Shall indicate country of Origin legibly and permanently and in a conspicuous place. It must also be in a close proximity and in comparable size to the name of country or locality other than the country of origin appears on the marking. Must be visible at point of purchase.	
<b>Physical characteristics</b>			
<b>Net Content</b>	Standard Measure	As Reported	
<b>Appearance and Odor</b>	Visual & Organoleptic	As Reported	
<b>pH Value</b>	Water Extraction, followed by analysis using pH meter	As reported	<BSch: When we measure pH, we normally perform it as-is for creams/lotions – we don't perform a water extraction. If they wish for us to prepare the sample prior to measuring pH, we need instructions on how they wish us to do so>
<b>Flash Point</b>	16 CFR 1500.43a 16 CFR 1500.3(c)(6)(iii)	Closed cup/Rapid Equilibrium	
<b>Physical Test on Container</b>			
<b>Physical Testing</b>		Overall Dimension (Length x Width x Height) Workmanship Stability Test Leakage Test Drop Test	

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Main Regulatory Requirements</b>			
<b>Heavy metal contamination (Pb, Cd, Hg, As, Sb)</b>	Acid digestion of the sample followed by ICP analysis	<b>US</b> 21 CFR 700.13. US FDA  Mercury: Less than 1 ppm for general cosmetics  <b>Canada</b> Health Canada Guidance on Heavy Metal Impurities in Cosmetics  Lead < 10ppm Arsenic < 3ppm Cadmium < 3ppm Mercury < 3ppm Antimony < 5ppm	
<b>Phthalates (DEHP)</b>	HPLC analysis	Prohibited in Hotlist	
<b>Microbial contamination</b>	USP <61>	Product Type	Total Plate Count + Yeast & Mold Limit Values
		All other Products	NMT 5,000 CFR per g or mL
<b>Microbial contamination</b>	USP <61>	<b>Canada</b>	
		Product Type	TPC Y&M
		Children & Infants	LT 100 CFU / mL or g LT 10 CFU / mL or g
		Other Products	LT 1,000 CFU / mL or g LT 100 CFU / mL or g
<b>Microbial contamination</b>	USP <62>	<b>US</b>	
		Microbial	Limit Values
		Escherichia coli	None detected
		Staphylococcus aureus	None detected
		Pseudomonas aeruginosa	None detected
<b>Microbial contamination</b>	USP <62>	<b>Canada</b> Candida albicans, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus shall be absent from all cosmetic product types	Health Canada acceptance criteria

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Efficacy of antimicrobial preservation</b>	PCPC Preservative Effectiveness	Day	Bacteria Fungi
		7	≥ 99.9% ≥ 90%
		14	≥ 99.9% ≥ 90%
		28	≥ 99.9% ≥ 90%
<b>Lead, Cadmium, Mercury and Chromium (VI)</b>	Sample digestion. Analysis conducted by Inductively Coupled Argon Plasma Spectrometry and UV-Visible Spectroscopy	<b>US</b> Toxics in Packaging law (Toxics in Packaging Clearinghouse)  California, Connecticut, Florida, Georgia, Illinois, Iowa, Maine, Maryland, Minnesota, Missouri, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, Wisconsin) ≤100 ppm (sum of lead, cadmium, mercury and chromium (VI))	Applicable to packaging materials
<b>Ingredient and labelling</b>			
<b>Toxicological risk assessment (TRA) on the formulation</b>	Review the hazard, exposure and risk on the full ingredient and evaluate the safety of the product by a Toxicologist	<b>US</b> FD&C Act Take reference to the definition of 16 CFR 1500.3  <b>Canada</b> Cosmetic Regulation of the Food and Drug Act; C.R.C., c.869 and Hotlist (List of prohibited and Restricted Cosmetics Ingredients)  Review the hazard, exposure and risk on the full ingredient and evaluate the safety of the product by a Toxicologist	Alternate hazard assessment tests may be deemed acceptable by the FDA or Health Canada for determining the safety of a product (e.g. in-vivo or in-vitro testing)
<b>Ingredient Review</b>	Review the full ingredient based on the regulatory requirement, against those prohibited and restricted listed in the regulations	<b>US</b> US FDA, Food Drug and Cosmetics Regulations (21 CFR 73, 74, 81, 82, 250 & 700 to 740)  <b>Canada</b> Sections 17-24 of Cosmetic Regulation of the Food and Drug Act; C.R.C, c.869 and Hotlist (List of Prohibited and Restricted Cosmetic Ingredients)	
<b>Package Label Review</b>	Package label based on the regulatory requirement	<b>US</b> Federal Food, Drug, and Cosmetic Act (FFDCA or FDCA), 21 CFR 701 & 740, Fair Packaging and Labeling Act  <b>Canada</b> Canada Food and Drug Act, Cosmetic Regulation, the Consumer Packaging and Labelling Act and Regulations Directions for safe use ( If applicable)  <b>Canada:</b> Canada Food and Drug Act, Cosmetic Regulation, the Consumer Packaging and Labelling Act and Regulations  Outer package  <b>Principle Display Panel (PDP)</b> - Product Quality - Net Quantity  <b>Information Panel</b> - Avoidable hazards and cautions - Name and address of the manufacturer - Ingredient declaration  <b>Inner Package</b> - Product Identity - Avoidable hazards and cautions - Name and Address of the manufacturer	

TEST PROPERTY	TEST METHOD	REQUIREMENTS	REMARKS
<b>Country of Origin Marking</b>	19 CFR 134.11	US Shall indicate country of Origin legibly and permanently and in a conspicuous place. It must also be in a close proximity and in comparable size to the name of country or locality other than the country of origin appears on the marking. Must be visible at point of purchase.	
<b>Physical characteristics</b>			
<b>Net Content</b>	Standard Measure	As Reported	
<b>Appearance and Odor</b>	Visual & Organoleptic	As Reported	
<b>pH Value</b>	Water Extraction, followed by analysis using pH meter	As reported	<BSch: When we measure pH, we normally perform it as-is for creams/lotions – we don't perform a water extraction. If they wish for us to prepare the sample prior to measuring pH, we need instructions on how they wish us to do so>

# ADDITIONAL REQUIREMENTS

## ADDITIONAL RESTRICTIONS TO BE FOLLOWED BY SUPPLIERS

### BIODEGRADABILITY

Surfactants, detergents, complexing agents and softeners should be sufficiently biodegradable. This normally means that the biodegradability should be more than 60% according to a relevant test method (e.g. OECD 301 B or ISO 9408).

### ODOUR

BESTSELLER expects that all products have a 'product specific smell', which can be tested with odour test SNV 195 651. Strong smells from garments can occur through a possible unauthorized chemical content, or bad practice in washing or airing processes prior to shipment. A non-product specific odour will be treated as a quality issue – and even if the garment is meeting the BCR, claims will be made to the supplier.

### MOULD

Spores and mycelia of mould should not be detected in any products. Suppliers must note key requirements on spraying of goods and containers to prevent mould during transportation of goods.

### TRANSPORTATION OF GOODS: CONTAINERS AND CARGO

Fumigating, gassing or spraying cargo or containers containing BESTSELLER products with any chemicals is banned. Levels of chemicals will be measured when the container reaches the port of destination. Levels must not exceed acceptable health and safety levels. Regardless of the source all costs in connection with cleaning containers, damage or loss of products and any resulting lost profit will be claimed.

# REACH AND SUBSTANCES OF VERY HIGH CONCERN

All BESTSELLER suppliers must abide by Regulation (EC) No 1907/2006, of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

REACH has been introduced to more effectively monitor and control the import of chemicals into the EU. It aims to ensure that all manufacturers and importers of chemicals identify the substances that are being used in their production, and to manage the risks that these chemicals may pose to human health and the environment.

**Concerning the REACH 'Substances of Very High Concern' (SVHCs) the BCR limit for all products and all packaging is 1000 ppm (0.1%) for each substance on the list, unless a lower limit is specified in this document.**

For an updated SVHC list please follow the below link (on May 31<sup>st</sup> 2016 there are 168 SVHCs and new SVHCs are added regularly):  
<http://echa.europa.eu/web/guest/candidate-list-table>

Suppliers must abide by the SVHC-list at all times and on request document this e.g. by providing tests, having quality systems in place, procedures and the like. Moreover, upon request suppliers are required to fill out a form within 10 days). We request that all BESTSELLER suppliers visit the webpage of the European Chemicals Agency (ECHA) (<http://echa.europa.eu/>) regularly and ensure that they are always fully up-to-date on the requirements of REACH.

# TESTING & CONTROL

## CONTROL

In order to comply with BESTSELLER's Chemical Restrictions (BCR), it is important that suppliers have full control and are aware of all chemicals that are being used throughout the entire production network.

Suppliers must ensure that all subcontractors, suppliers of materials and accessories (including labels and packaging), dye-houses, print-houses, tanneries, carriers, etc., are fully aware of the BCR and agree to strictly follow them. Suppliers must ensure that all parts of their production network have the latest version of the BCR and that they assist in educating all parts of the supply chain in meeting these requirements – and only work with suppliers that are able to do so. Suppliers should work to understand the chemical aspects of the supply chain to effectively identify and control the risk areas.

Suppliers should select professional and well-run suppliers of materials and dyeing / printing facilities, and ensure the use of dyestuffs, printing chemicals and any other production-process chemicals from reputable and well-known manufacturers.

Suppliers must assume responsibility in ensuring that the production network is constantly informed of BESTSELLER's requirements – and that the materials coming into the factory are able to meet the standard set in the BCR. Material data sheets should be acquired from dye-houses and print-houses to make sure that no banned or restricted chemicals are used.

## THE BESTSELLER CHEMICAL TESTING PROGRAMME

BESTSELLER requires chemical tests on products and has a comprehensive chemical testing programme in place. There is further information on these testing requirements in the '**Chemical Testing Programme**' which is available on the supplier portal and from your local purchase office. Testing and monitoring is coordinated through both the local purchase offices and buying departments in Denmark. All suppliers must meet agreed testing requirements - this is non-negotiable when producing articles for BESTSELLER.

# APPENDIX 1

## LIST OF NOT ALLOWED FLAME RETARDANTS

COMPOUND	CAS NUMBER
Tris (2,3-dibromopropyl) phosphate (TRIS)	126-72-7
Tris (2-chloroethyl) phosphate (TCEP)	115-96-8
Tris (1-aziridinyl)-phosphine oxide (TEPA)	545-55-1
Penta-bromodiphenyl ether (pentaBDE)	32534-81-9
Octa-bromodiphenyl ether (octaBDE)	32536-52-0
Hexa-bromocyclododecane (HBCDD)	3194-55-6
Deca-bromodiphenyl ether (decaBDE)	1163-19-5
Tetrabromobisphenol A (TBBP A)	79-94-7
Polybromobiphenyls (PBB)	59536-65-1
Bis(2,3-dibromopropyl) phosphate (BIS)	5412-25-9
2,2-bis(bromomethyl)-1,3-propanediol (BBMP)	3296-90-0
Tris-(1,3-dichlor-2-propyl)phosphate (TDCPP)	13674-87-8
Trixylylphosphate (TXP)	25155-23-1

## LIST OF RESTRICTED CHLORINATED ORGANIC CARRIERS

COMPOUND	CAS NUMBER	COMPOUND	CAS NUMBER
2-Chlorotoluene	95-49-8	Pentachlorotoluene	877-11-2
3-Chlorotoluene	108-41-8	1,3-Dichlorobenzene	541-73-1
4-Chlorotoluene	106-43-4	1,4-Dichlorobenzene	106-46-7
2,3-Dichlorotoluene	32768-54-0	1,2,3-Trichlorobenzene	87-61-6
2,4-Dichlorotoluene	95-73-8	1,2,4-Trichlorobenzene	120-82-1
2,5-Dichlorotoluene	19398-61-9	1,3,5-Trichlorobenzene	108-70-3
2,6-Dichlorotoluene	118-69-4	1,2,3,4-Tetrachlorobenzene	634-66-2
3,4-Dichlorotoluene	95-75-0	1,2,3,5-Tetrachlorobenzene	634-90-2
2,3,6-Trichlorotoluene	2077-46-5	1,2,4,5-Tetrachlorobenzene	95-94-3
2,4,5-Trichlorotoluene	6639-30-1	Pentachlorobenzene	608-93-5
2,3,4,5-Tetrachlorotoluene	76057-12-0	Hexachlorobenzene	118-74-1
2,3,5,6-Tetrachlorotoluene	875-40-1	1,2-Dichlorobenzene	95-50-1



**LIST OF RESTRICTED ISOCYANATES**

COMPOUND	CAS NUMBER
Toluene diisocyanate (TDI)	584-84-9, 91-08-7
Diphenylmethane diisocyanate (MDI)	101-68-8
Hexamethylene diisocyanate (HDI)	822-06-0
Isophorone diisocyanate (IPDI)	4098-71-9
Tetramethylxylene diisocyanate (TMXDI)	2778-42-9

**LIST OF NOT ALLOWED PESTICIDES**

COMPOUND	CAS NUMBER	COMPOUND	CAS NUMBER
2-(2,4,5-Trichlorophenoxy) propionic acid, salts, compounds ("2,4,5-T")	93-76-5	Fenvalerate	51630-58-1
2,4-Dichlorophenoxyacetic acid, salts & compounds ("2,4-D")	94-75-7	Heptachlor	76-44-8
Azinophosmethyl	86-50-0	Heptachloroepoxide	1024-57-3
Azinophosethyl	2642-71-9	Hexachlorobenzene	118-74-1
Aldrine	309-00-2	Hexachlorocyclohexane, alpha	319-84-6
Bromophos-ethyl	4824-78-6	Hexachlorocyclohexane, beta	319-85-7
Captafol	2425-06-1	Hexachlorocyclohexane, gamma	319-86-8
Carbaryl	63-25-2	Isodrin	465-73-6
Chlordane	57-74-9	Kelevane	4234-79-1
Chlordimeform	6164-98-3	Kepone	143-50-0
Chlorfenvinphos	470-90-6	Lindane	58-89-9
Coumaphos	56-72-4	Malathion	121-75-5
Cyfluthrin	68359-37-5	MCPA	94-74-6
Cyhalothrin	91465-08-6	MCPB	94-81-5
Cypermethrin	52315-07-8	Mecoprop	93-65-2
DEF	78-48-8	Metamidophos	10265-92-6
Deltamethrin	52918-63-5	Methoxychlor	72-43-5
DDD	53-19-0, 72-54-8	Mirex	2385-85-5
DDE	3424-82-6, 72-55-9	Monocrotophos	6923-22-4
DDT	50-29-3, 789-02-6	Parathion	56-38-2
Diazinon	333-41-5	Parathion-methyl	298-00-0
Dichlorprop	120-36-2	Perthane	72-56-0
Dicrotophos	141-66-2	Phosdrin/ Mevinphos	7786-34-7
Dieldrine	60-57-1	Propethamphos	31218-83-4
Dimethoate	60-51-5	Profenophos	41198-08-7
Dinoseb it salts and acetate	88-85-7 et al	Quinalphos	13593-03-8
Endosulfan, alpha	959-98-8	Strobane	8001-50-1
Endosulfan, beta	33213-65-9	Telodrin	297-78-9
Endrine	72-20-8	Toxaphene	8001-35-2
Esfenvalerate	66230-04-4	Trifluralin	1582-09-8

**LIST OF RESTRICTED CHLORINATED PHENOLS**

COMPOUND	CAS NUMBER	COMPOUND	CAS NUMBER
2,3,5,6-Tetrachlorophenol (a TeCP)	935-95-5	2,3,6-Trichlorophenol (a TrCP)	933-75-5
2,3,4,6-Tetrachlorophenol (a TeCP)	58-90-2	2,4,5-Trichlorophenol (a TrCP)	95-95-4
2,3,4,5-Tetrachlorophenol (a TeCP)	4901-51-3	2,4,6-Trichlorophenol (a TrCP)	88-06-2
2,3,4-Trichlorophenol (a TrCP)	15950-66-0	3,4,5-Trichlorophenol (a TrCP)	609-19-8
2,3,5-Trichlorophenol (a TrCP)	933-78-8		

**LIST OF RESTRICTED PHTHALTES**

COMPOUND	CAS NUMBER	COMPOUND	CAS NUMBER
Di-Iso-nonylphthalate (DINP)	28553-12-0	Di(2-methoxyethyl) phthalate (DMEP)	117-82-8
Di-n-octylphthalate (DNOP)	117-84-0	Di-n-hexylphthalate (DnHP)	84-75-3
Di(2-ethylhexyl)-phthalate (DEHP)	117-81-7	Diethylphthalate (DEP)	84-66-2
Diisodecylphthalate (DIDP)	26761-40-0	Diisopentylphthalate (DIPP)	605-50-5
Butylbenzylphthalate (BBP)	85-68-7	n-Pentylisopentylphthalate (NPIPP)	776297-69-9
Dibutylphthalate (DBP)	84-74-2	Di-n-pentylphthalate (DPP)	131-18-0
Diisobutylphthalate (DIBP)	131-11-3	Dihexylphthalate, branched + linear	68515-50-4
Di(C7-C11 alkyl) phthalate (DHNU), linear + branched	68515-42-4	Dimethylphthalate (DMP)	131-11-3
Di(C6-C8 alkyl) phthalate (DIHP), branched, C7 rich	71888-89-6	1,2-Benzenedicarboxylic acid, dipentylester, branched + linear	84777-06-0

**LIST OF OTHER SOLVENTS / VOLATILE ORGANIC COMPOUNDS (VOCs)**

COMPOUND	CAS NUMBER
1,1,1-trichloroethane	71-55-6
Acetone	67-64-1
Cyclohexanone	108-94-1
Ethyl acetate	141-78-6
Isophorone	78-59-1
Tetrachloroethylene (perchloroethylene)	127-18-4
Xylenes (Dimethylbenzenes)	1330-20-7

**BESTSELLER**®