



PIGMENT TESTING & ANALYSIS COMPLIANCE

Li Pigments excels at providing pigments that follow the most current worldwide regulations and guidelines to ensure a high level of safety with minimal health risk for our customers.

Li Pigments abides to global regulations of permanent makeup and we also abide to EU regulations within the EU.

With 30+ years of no adverse reactions, our tried & true products are still available. New EU REACH compliant pigments have also been added to our inventory to accommodate our customers and clients within the EU.

The Li Pigments products that cannot be sold within the EU do not contain and will not ever contain any banned raw pigment powders or banned chemicals/carriers.

Any Li Pigments products that are not EU Compliant previously passed the EU-Resolution ResAP(2008)1 with certificate validation.

TESTING & ANALYSIS OF MICRO-PIGMENTATION PRODUCTS DIRECTIVE 76/768/EEC, ANNEX VI PART I & II EU-RESOLUTION RESAP (2008)1

Agents present in Permanent Cosmetic/Tattoo products manufactured by Li Pigments, but not limited to:

Coloring Agents allowed for use in Cosmetic Products:

USA: As outlined in 21 CFR 73 & 74
EU: As outlined in Directive 76/768/EEC; ANNEX IV PART I & II
EU-Resolution ResAP(2008)1

Preservative Agents allowed for use in Cosmetic Products.:

Preservatives are substances added to cosmetic products for the primary purpose of inhibiting microbial growth.

USA: Not applicable
EU: As outlined in Directive 76/768/EEC, ANNEX VI PART I & II EU-Resolution ResAP(2008)1

Dispersion/Suspension Liquids/Substances Restrictions & Provisions of Cosmetic Products:

USA: As outlined in 21 CFR, Parts 250.250 and 700.11 through 700.23)
EU: Biocidal Regulation (EU) No (528/2012) of the European Parliament & Council
EU: As outlined in Directive 76/768/EEC, ANNEX II; ANNEX III PART I & II EU-Resolution ResAP(2008)1

Labeling Guidelines & Regulations for use on Cosmetic Products:

USA: As outlined in 21 CFR, parts 700 to 740
EU: As outlined in Directive 76/768/EEC, Article 6 EU-Resolution ResAP(2008)1
EU: Cosmetics Regulation (EC) No (1223/2009) of the European Parliament & Council
EU: CLP (1272/2008) CLP regulation (classification, labeling, packaging) which defines the classification of chemicals

Li Pigments has implemented an additional label marker on the AQUA, VELVET, and Li SCALP pigment lines to make it clear and concise as to whether a pigment is compliant for their area. Order forms are also clearly marked.

“NOT TO BE SOLD TO EU” LABEL DESIGNATION: The “NOT TO BE SOLD TO EU” label designation is to communicate that this product can be sold to customers located outside of the EU. These products do not meet EU Reach regulations and can not be sold to EU customers. If pigments do not include this label marker, then that is a EU REACH compliant product.

Li Pigments adheres to labeling laws and regulations worldwide to provide all of our customers with as much detailed information about our products. Pigment labeling information is made available for customers looking for more details about the symbols and text used on our product labels. Customers may scan the QR code present on the product label, or refer to the product information sheet available on our website, www.LiPigments.com.

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Li Pigments will always abide by all global laws and limitations of PMU and we wish to provide our quality micro-pigmentation products worldwide. We are proud to have refined our formulations and added a number of EU compliant pigments to our inventory for our trusted and valued customers located in the EU.

The European Union has implemented Regulation 1907/2006 Annex XVII (REACH) of the European Parliament and the Council. As a result, effective January 2022, EU REACH has identified over 4,000 ingredients that are now restricted or no longer permitted for use in tattoo inks and permanent makeup (micro-pigmentation pigments). The restriction also introduces maximum concentration limits for individuals or groups of substances used in tattoo inks and permanent makeup pigments.

TESTING & ANALYSIS OF MICRO-PIGMENTATION PRODUCTS REGULATION 1907/2006 ANNEX XVII (REACH)

Part 1: Document Check

On the basis of formulations, it is ruled out that prohibited substances are deliberately used in the colour.

Part 2: Free Amines

Method: Extraction with MeOH, Analysis with GC/MS.

Limit: 5 ppm; limit of quantitation: 5ppm.

4-Aminobiphenyl**	Benzidine**
4-Chloro-o-toluidine**	2-Naphtylamine**
4-o-Tolylazo-o-toluidin**	5-Nitro-o-toluidine**
4-Chloroaniline**	4-Methoxy-m-phenylenediamine**
4,4'-Methylenedianiline**	3,3'-Dichlorobenzidine**
3,3'-Dimethoxybenzidine**	4,4'-Bi-o-Toluidin**
4,4'-Methylenedi-o-toluidine**	6-Methoxy-m-toluidine**
4,4'-Methylenebis-(2-chloroaniline)**	4-Methyl-m-phenylenediamine**
o-Anisidine**	4-Aminoazobenzene**
2-Methyl-p-phenylenediamin**	4-Amino-3-florophenol**
4,4'-Oxydianiline**	4,4'-Thiodianiline**
o-Toluidine**	2,4,5-Trimethylaniline**
p-Phenylenediamine**	Aniline**
p-Toluidine**	Sulfanilic acid**
2,6-Xylidine	6-Amino-2-ethoxynaphtaline
2,4-Xylidine	
**soluble	

Part Part 3: Screening incl. testing for prohibited preservatives and phthalates*

List of tested substances. Extraction in methanol, analysis with GC/MS and HPLC/DAD.

Phenol	2-Phenylphenol (OPP)
Benzoic acid	Benzisothiazolinone (BIT)
2-Phenoxyethanol	Chloramin T
4-Chlor-3-methylphenol (CMK)	Octhilinone (ISO); 2-octyl-2H-isothiazol-3-one
Formaldehyde	Triclosan
Acetaldehyde	2-Thiocyanomethylthio)benzothiozol (TCMTB) Busan
5-Chloro-2-methyl-3(2H)-isothiazolone (CIT)	5-Chloro-2-methyl-3(2H)-isothiazolone (CIT)
2-Methyl-3(2H)-Isothiazolone (MIT)	4,5-Dichlor-2-octyl-2H-isothiazol-3-on
Diisobutylphthalat (DIBP)	Dibutylphthalat (DBP)
Di(2-ethylhexyl)-Phthalat (DEHP)	Benzylbutylphthalat (BBP)
Di-iso-heptylphthalat (DIHP)	Bis(2-methoxyethyl)phthalat (DMEP)
Diisopentylphthalat (DIPP)	Di-n-pentylphthalat (DPP)
Dicyclohexylphthalat (DcHP)	Di-n-hexylphthalat (DnHP)
Diisohexylphthalat (DIHP)	n-Pentyl-isopentylphthalat (nPiP)
1,2-Benzenedicarboxylic acid, di-C7-11, branched and linear alkyl esters (DUP) (DHNUP)	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear, DiPP, nPiP

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TESTING & ANALYSIS OF MICROPIGMENTATION PRODUCTS REGULATION 1907/2006 ANNEX XVII (REACH) CONTINUED

Part 4: Heavy Metals

Methods:

Total digestion acc. ASU K 84.00.29:2016-07; ICP-OES analysis DIN EN IOS 11885:2009-09. ICP-MS acc. to DIN EN ISO 17294-1:2017-1 Soluble: Prior, G. (2014), Tattoo Inks: Analysis, Pigments, Legislation. Berlin: epubli. CTL, p 83. Chromium (VI): DIN EN ISO 17075-1:2017-05 Organometallic tin: DIN CEN ISO/TS 16179:2012-12

Limit of quantitation: equal or below the limit respectively.

Mercury	0.5 ppm
Nickel	5 ppm
Organometallic tin	0.5 ppm
Antimony	0.5 ppm
Arsenic	0.5 ppm
Barium**	500 ppm
Cadmium	0.5 ppm
Chromium as Cr(VI)	0.5 ppm
Cobalt	0.5 ppm
Copper**	250 ppm
Zinc**	2000 ppm
Lead	0.7 ppm
Selenium	2 ppm
**soluble	

Part 5: Polyaromatic hydrocarbons

Method: AFPS GS 2019:01 PAK, extraction in toluene

Limit: 0.5 ppm / BaP 5 ppb;

limit of quantitation: 0.5 ppm / BaP 5 ppb

Naphthalene	Acenaphthalene	Acenaphthene
Fluorene	Phenanthrene	Anthracene
Fluoranthene	Pyrene	Benzo[a]anthracene
Chrysene	Benzo[b]fluoranthene	Benzo[k]fluoranthene
Benzo[a]pyrene	Dibenzo[ah]anthracene	Indeno[1,2,3,cd]pyrene
Benzo[ghi]perylene	Benzo[j]fluoranthene	Benzo[e]pyrene
Cyclopenta[cd]pyrene	Dibenzo[al]pyrene	Dibenzo[ae]pyrene
Dibenzo[ai]pyrene	Dibenzo[ah]pyrene	1-Methylpyrene
Benzo[c]fluorene	5-Methylchrysene	

Part 6: Sterility

(microbiological test)

Limit of quantitation: < 10 CFU/g

Test conducted by an accredited external laboratory.

Spores of aerobes spore-forming, quantitative*	In-house method
Spores of anaerobes spore-forming, quantitative*	In-house method
Bacillus cereus presumptive, quantitative	§64 LFGB 00.00-33, mod.
Sulphite reducing clostridia, quantitative	§64 LFGB 06.00-39, mod.
Total viable count, aerobes mesophil 30°C	§64 LFGB 00.00-88/2, mod.
Total viable count, anaerobes mesophil 30°C*	In-house method
Pseudomonas sp., quantitative	§64 LFGB 06.00-43, mod.