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# **Quality and Compliance Technical Dossier**

For use in tattoo/permanent make-up procedures by professional artists only

Name: Blue Eyes SKU: LXBE Lot: 12233









Avoid sunlight or high temperatures Recommended storage conditions: 5°C/41°F to 35°C/95°F

**Complete Ingredients List (descending order):** WATER, BLUE 15:3 (CI:74160), MODIFIED ACRYLIC POLYMER, GLYCERIN, PROPYLENE GLYCOL, TEA, WHITE 6 (CI:77891), ACRYLATES COPOLYMERS, ETHOXYLATED FATTY ALCOHOLS, SORBITOL, BENZYL ALCOHOL, DISODIUM SALT, MINERAL OIL, AMMONIUM HYDROXIDE (pH REGULATOR)

No methanol or isopropyl alcohol is used in any formulations of this brand unless designated

## **Declaration of Quality, Compliance and Analytical Summary:**

### Heavy Metals

All results generated from Inductively Coupled Plasma Mass Spectrometry (ICP-MS) sample prep and analysis

| Property         | EC Number | CAS Number | Limit (% by weight and ppm)   |
|------------------|-----------|------------|---|
| Heavy Metals     |           |            | DOES NOT EXCEED THE ESTABLISHED LIMIT AS<br>IN COMMISSION REGULATION (EU) 2020/2081 |
| Antimony         | 231-146-5 | 7440-36-0  | ≤0.00005% (0.5ppm)  |
| Arsenic          | 231-148-6 | 7440-38-2  | ≤0.00005% (0.5ppm)  |
| Cadmium          | 231-152-8 | 7440-43-9  | ≤0.00005% (0.5ppm)  |
| Cobalt           | 231-158-0 | 7440-48-4  | ≤0.00005% (0.5ppm)  |
| Mercury          | 231-106-7 | 7439-97-6  | ≤0.00005% (0.5ppm)  |
| Nickel           | 231-111-4 | 7440-02-0  | ≤0.0005% (5.0ppm)   |
| Lead             | 231-100-4 | 7439-92-1  | ≤0.00007% (0.7ppm)  |
| Selenium         | 231-957-4 | 7782-49-2  | ≤0.0002% (2.0ppm)   |
| Barium (Soluble) | 231-149-1 | 7440-39-3  | ≤0.05% (500ppm)   |
| Zinc (soluble)   | 231-175-3 | 7440-66-6  | ≤0.2% (2000ppm)   |

| Copper (soluble)   | 231-159-6 | 7440-50-8 | ≤0.025% (250ppm)   |
|--------------------|-----------|-----------|--------------------|
| Chromium VI        | 231-157-5 | 7440-47-3 | ≤0.00005% (0.5ppm) |
| Organometallic Tin | 231-141-8 | 7440-31-5 | ≤0.00005% (0.5ppm) |

Polycyclic-aromatic Hydrocarbons (PAH) All results generated from EPA3550C + EPA8270E methods using Gas Chromatography Mass Spectrometry (GC-MS) sample prep and analysis

| Property                        | EC Number | CAS Number | Limit (% by weight, ppm)  |
|---------------------------------|-----------|------------|---|
| Polyaromatic Hydrocarbons (PAH) |           |            | DOES NOT EXCEED THE<br>ESTABLISHED LIMIT AS IN<br>COMMISSION REGULATION<br>(EU) 2020/2081 |
| Naphthalene                     | 202-049-5 | 91-20-3    | ≤0.00005% (0.5ppm)  |
| Acenaphthylene                  | 201-469-6 | 83-32-9    | ≤0.00005% (0.5ppm)  |
| Acenaphthene                    | 201-469-6 | 83-32-9    | ≤0.00005% (0.5ppm)  |
| Fluorene                        | 201-695-5 | 86-73-7    | ≤0.00005% (0.5ppm)  |
| Phenanthrene                    | 201-581-5 | 85-01-8    | ≤0.00005% (0.5ppm)  |
| Anthracene                      | 204-371-1 | 120-12-7   | ≤0.00005% (0.5ppm)  |
| Fluoranthene                    | 205-912-4 | 206-44-0   | ≤0.00005% (0.5ppm)  |
| Pyrene                          | 204-927-3 | 129-00-0   | ≤0.00005% (0.5ppm)  |
| Benz[a]anthracene               | 200-280-6 | 56-55-3    | ≤0.00005% (0.5ppm)  |
| Chrysene                        | 205-923-4 | 218-01-9   | ≤0.00005% (0.5ppm)  |
| Benzo[b]fluoranthene            | 205-911-9 | 205-99-2   | ≤0.00005% (0.5ppm)  |
| Benzo[j]fluoranthene            | 205-910-3 | 205-82-3   | ≤0.00005% (0.5ppm)  |
| Benzo[k]fluoranthrene           | 205-916-6 | 207-08-9   | ≤0.00005% (0.5ppm)  |
| Benzo[e]pyrene                  | 205-892-7 | 192-97-2   | ≤0.00005% (0.5ppm)  |
| Benzo[a]pyrene                  | 200-028-5 | 50-32-8    | ≤0.0000005% (0.005ppm)  |
| Indeno[1,2,3-cd]pyrene          | 205-893-2 | 193-39-5   | ≤0.00005% (0.5ppm)  |
| Dibenz[a,h]anthracene           | 200-181-8 | 53-70-3    | ≤0.00005% (0.5ppm)  |
| Benzo[ghi]perylene              | 205-883-8 | 191-24-2   | ≤0.00005% (0.5ppm)  |

<u>Amines</u> All results generated from ISO 14362-1:2017 method with determination completed with GC-MS and additional Liquid Chromatography Mass Spectrometry (LC-MS) sample prep and analysis for some analytes of interest

| Property                               | EC Number | CAS Number | Limit (% by weight, ppm)  |
|--|-----------|------------|---|
| Amines                                 |           |            | DOES NOT EXCEED THE<br>ESTABLISHED LIMIT AS IN<br>COMMISSION REGULATION<br>(EU) 2020/2081 |
| o-Anisidine (Soluble)                  | 201-963-1 | 90-04-0    | ≤0.0005% (5.0ppm)   |
| o-toluidine (Soluble)                  | 202-429-0 | 95-53-4    | ≤0.0005% (5.0ppm)   |
| 3,3'-dichlorobenzidine (Soluble)       | 202-109-0 | 91-94-1    | ≤0.0005% (5.0ppm)   |
| 4-methyl-m- phenylenediamine (Soluble) | 202-453-1 | 95-80-7    | ≤0.0005% (5.0ppm)   |
| 4-chloroaniline (Soluble)              | 203-401-0 | 106-47-8   | ≤0.0005% (5.0ppm)   |

| 5-nitro-o-toluidine (Soluble)                       | 202-765-8 | 99-55-8     | ≤0.0005% (5.0ppm) |
|---|-----------|-------------|-------------------|
| 3,3'-dimethoxybenzidine (Soluble)                   | 204-355-4 | 119-90-4    | ≤0.0005% (5.0ppm) |
| 4,4'-bi-o-toluidine (Soluble)                       | 204-358-0 | 119-93-7    | ≤0.0005% (5.0ppm) |
| 4,4'-Thiodianiline (Soluble)                        | 205-370-9 | 139-65-1    | ≤0.0005% (5.0ppm) |
| 4-chloro-o-toluidine (Soluble)                      | 202-441-6 | 95-69-2     | ≤0.0005% (5.0ppm) |
| 2-naphthylamine (Soluble)                           | 202-080-4 | 91-59-8     | ≤0.0005% (5.0ppm) |
| Aniline (Soluble)                                   | 200-539-3 | 62-53-3     | ≤0.0005% (5.0ppm) |
| Benzidine (Soluble)                                 | 202-199-1 | 92-87-5     | ≤0.0005% (5.0ppm) |
| p-toluidine (Soluble)                               | 203-403-1 | 106-49-0    | ≤0.0005% (5.0ppm) |
| 2-methyl-p-phenylenediamine (Soluble)               | 202-442-1 | 95-70-5     | ≤0.0005% (5.0ppm) |
| Biphenyl-4-ylamine (Soluble)                        | 202-177-1 | 92-67-1     | ≤0.0005% (5.0ppm) |
| 4-o-tolylazo-o-toluidine (Soluble)                  | 202-591-2 | 97-56-3     | ≤0.0005% (5.0ppm) |
| 4-methoxy-m- phenylenediamine (Soluble)             | 210-406-1 | 615-05-4    | ≤0.0005% (5.0ppm) |
| 4,4'-methylenedianiline (Soluble)                   | 202-974-4 | 101-77-9    | ≤0.0005% (5.0ppm) |
| 4,4'-methylenedi-o-toluidine (Soluble)              | 212-658-8 | 838-88-0    | ≤0.0005% (5.0ppm) |
| 6-methoxy-m-toluidine (Soluble)                     | 204-419-1 | 120-71-8    | ≤0.0005% (5.0ppm) |
| 4,4'- methylene-bis-[2-chloro<br>aniline] (Soluble) | 202-918-9 | 101-14-4    | ≤0.0005% (5.0ppm) |
| 4,4'-oxydianiline (Soluble)                         | 202-977-0 | 101-80-4    | ≤0.0005% (5.0ppm) |
| 2,4,5-trimethylaniline (Soluble)                    | 205-282-0 | 137-17-7    | ≤0.0005% (5.0ppm) |
| 4-Aminoazobenzene (Soluble)                         | 200-453-6 | 60-09-3     | ≤0.0005% (5.0ppm) |
| p-Phenylenediamine (Soluble)                        | 203-404-7 | 106-50-3    | ≤0.0005% (5.0ppm) |
| Sulphanilic acid (Soluble)                          | 204-482-5 | 121-57-3    | ≤0.0005% (5.0ppm) |
| 4-amino-3-fluorophenol (Soluble)                    | 402-230-0 | 399-95-1    | ≤0.0005% (5.0ppm) |
| 2,6-xylidine  | 201-758-7 | 87-62-7     | ≤0.0005% (5.0ppm) |
| 6-amino-2-ethoxynaphthaline                         |           | 293733-21-8 | ≤0.0005% (5.0ppm) |
| 2,4-xylidine  | 202-440-0 | 95-68-1     | ≤0.0005% (5.0ppm) |

### **General Screening of Formulation Contaminants**

High Pressure Liquid Chromatography (HPLC) and GC-MS are analytical tools used to conduct further testing for any detectable carcinogens, reproductive toxicants, skin sensitizers, skin and eye corrosives/irritants not disclosed in raw materials or found as residuals/contaminants in finished formulation (ex. aldehydes, benzenes, additional amines, etc). The product listed herein complies with the standards described in EU Regulation 2020/2081 REACH Annex XVII and outlined with limits below

| Concern  | Regulatory Category   | Limit  |
|--|---|--|
| Carcinogen/Mutagen                             | a substance classified in Part 3 of Annex VI to Regulation (EC) No<br>1272/2008 as carcinogen category 1A, 1B or 2, or germ cell<br>mutagen category 1A, 1B or 2  | 0.00005% by weight;<br>0.5ppm  |
| Reproductive<br>Toxicant<br>Skin Sensitizer    | a substance classified in Part 3 of Annex VI to Regulation (EC) No<br>1272/2008 as reproductive toxicant category 1A, 1B or 2<br>a substance classified in Part 3 of Annex VI to Regulation (EC) No   | 0.001% by weight;<br>10ppm<br>0.001% by weight;  |
| Skin Corrosive/ Skin<br>Irritant/ Eye Irritant | 1272/2008 as skin sensitiser category 1, 1A or 1B<br>a substance classified in Part 3 of Annex VI to Regulation (EC) No<br>1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant<br>category 2, or as serious eye damage category 1 or eye irritant<br>category 2 | 10ppm<br>0.1% by weight if solely<br>used as a pH regulator;<br>0.01% by weight in all<br>other cases (100ppm) |

| Annex II Substance | a substance listed in Annex II to Regulation (EC) No 1223/2009:<br>Rinse off products, Not to be used in products applied on mucous<br>membranes, Not to be used in eye products | 0.00005% by weight;<br>0.5ppm |
|--------------------|--|-------------------------------|
|--------------------|--|-------------------------------|

All testing is completed by 3<sup>rd</sup> party laboratories with verified method development and validation procedures for each test and product type. Testing is completed on both raw materials and finished product to ensure quality and safety. Please consult the safety data sheet (SDS) of each product for further safety information.

Ink Projects has reviewed the information provided by our raw materials suppliers, checked through 3rd party lab testing, and can confirm all our inks are in full compliance with the REACH Resolution 1907/2006, as amended (including Commission Regulation (EU) 2020/2081), nor do they contain any Substances of Very High Concern (SVHC) in concentrations above 0.1% by weight, are not classified as a hazardous material under CLP (EC 1272/2008/EC), and are in full compliance with BPR (EC 528/2012/EC). Ink Projects will continue to monitor relevant changes in REACH, ECHA, CLP, BPR and our raw materials provided by our suppliers to keep this statement accurate.

Quality Guarantee from Ink Projects Quality & Safety Team

Tric Gurthuran Х

Quality & Safety Manager

