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Quality and Compliance Technical Dossier

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Issue Date: 20 December 2021

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

Name: Berry
SKU: LXB
Lot: 12369









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

Complete Ingredients List (descending order): WHITE 6 (CI:77891), WATER, RED 170 (CI:12475), MODIFIED ACRYLIC POLYMER, GLYCERIN, PROPYLENE GLYCOL, TEA, ACRYLATES COPOLYMERS, ETHOXYLATED FATTY ALCOHOLS, SORBITOL, BENZYL ALCOHOL, DISODIUM SALT, MINERAL OIL, AMMONIUM HYDROXIDE (pH REGULATOR), BLUE 15 (CI:74160)

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 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 ESTABLISHED LIMIT AS IN COMMISSION REGULATION (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)

Amines

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 ESTABLISHED LIMIT AS IN COMMISSION REGULATION (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 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 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2	0.00005% by weight; 0.5ppm
Reproductive Toxicant	a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2	0.001% by weight; 10ppm
Skin Sensitizer	a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B	0.001% by weight; 10ppm
Skin Corrosive/ Skin Irritant/ Eye Irritant	a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2	0.1% by weight if solely used as a pH regulator; 0.01% by weight in all other cases (100ppm)

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

All testing is completed by 3rd 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

X Eric Gurtkuran

Quality & Safety Manager

