Etalon Mix

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Quality and Compliance Technical Dossier

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

Name: Opal №2

Lot: 2397

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Complete Ingredients List (descending order): Water (Aqua), Glycerin, PEG-8 (polyethylene glycol), Polyvinylpyrrolidone, Hamamelis Virginiana Extract, C.I. 200310 (Pigment Yellow 155), C.I. 77491 (Iron oxide red), C.I. 77499 (black iron oxide), C.I. 56110 (PIGMENT RED 254), C.I. 77266 (Carbon black).



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

Русский

1. Только для профессионального использования
2. Хорошо встряхните перед использованием
3. Применение данного продукта может вызывать аллергическую реакцию. Требуется провести пробу на аллергию.
4. Стерильно
5. Срок годности после вскрытия 12 месяцев
6. Не тестируется на животных
7. Беречь от попадания прямого солнечного света
8. Соблюдать температурный режим (от +5 до +30)

English

1. Professional use only
2. Shake well before use
3. This product may cause an allergic reaction. Patch test prior to application.
4. Sterile
5. 12 months from open
6. No animal testing
7. Don't leave out in sun
8. keep above freezing (from +5 to +30)

Czech

1. Pouze pro profesionální použití
2. Před použitím dobře protřepejte
3. Použití tohoto produktu může způsobit alergickou reakci. Je nutný test na alergii
4. Sterilní
5. Doba použitelnosti po otevření 12 měsíců
6. Netestováno na zvířatech
7. Chraňte před přímým slunečním zářením
8. dodržujte teplotní režim (od +5 do +30)

Espanol

1. Solo uso profesional
2. Agitar antes de Usar
3. Puede provocar reacciones alérgicas. Probar en una zona pequeña antes de la aplicación.
4. Esterilizado
5. 12 meses desde aperture
6. Sin pruebas en animals
7. No dejalar sol
8. mantener a temperaturas superiores a la congelación (de +5 a +30)

Français

1. Pour un usage professionnel seulement
2. Bien agiter avant l'usage
3. précautions d'emploi peut provoquer une réaction allergique il est conseillé de faire un test cutané avant utilisation pour vérifier une possible réaction allergique.
4. Stérile
5. 12 mois après ouverture
6. Non testé sur les animaux
7. Ne pas exposer au soleil
8. conserver à une température au-delà du seuil du congélation (de +5 à +30)

Deutsch

1. Nur für professionell Gebrauch
2. Vor Gebrauch gut schütteln
3. Dieses Produkt kann eine allergische Reaktion auslösen. Vor dem Anwenden auf einer kleinen Hautpartie ausprobieren.
4. Zertifiziert steril
5. 12 Monate nach dem Öffnen haltbar
6. Keine Tierversuche
7. Vor direkter Sonneneinstrahlung schützen
8. über dem Gefrierpunkt halten (von +5 bis +30)

Polski

1. Tylko do użytku profesjonalnego
2. Dobrze wstrząśnij przed użyciem
3. Może powodować reakcję alergiczną skóry. Test płatkowy przed aplikacją.
4. Jałowy
5. 12 miesięcy od otwarcia pojemnika
6. Nie testowane na zwierzętach
7. Chronić przed bezpośrednim nasłonecznieniem
8. utrzymuj temperaturę (od +5 do +30)

Magyar

1. Csak professzionális használatra
2. Használat előtt jól fel kell rázni
3. A termék allergiás reakciót válthat ki. Alkalmazása előtt végezzen allergiatesztet
4. Steril
5. A felbontástól számított 12 hónapig felhasználható
6. Állatkísérletmentes
7. Ne hagyja kint a napon
8. fagypont felett tárolja (+5 és +30 között)

Declaration of Quality, Compliance and Analytical Summary:

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*
Aniline (Soluble)	200-539-3	62-53-3	≤0.0005% (5.0ppm)
Benzidine (Soluble)	202-199-1	92-87-5	≤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)
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)
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)
2,4-xylidine	202-440-0	95-68-1	≤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)
4-Aminoazobenzene (Soluble)	200-453-6	60-09-3	≤0.0005% (5.0ppm)

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)
Barium (Soluble)	231-149-1	7440-39-3	≤0.05% (500ppm)
Cadmium	231-152-8	7440-43-9	≤0.00005% (0.5ppm)
Cobalt	231-158-0	7440-48-4	≤0.00005% (0.5ppm)
Chromium VI	231-157-5	7440-47-3	≤0.00005% (0.5ppm)
Copper (soluble)	231-159-6	7440-50-8	≤0.025% (250ppm)
Lead	231-100-4	7439-92-1	≤0.00007% (0.7ppm)
Mercury	231-106-7	7439-97-6	≤0.00005% (0.5ppm)
Nickel	231-111-4	7440-02-0	≤0.0005% (5.0ppm)
Organometallic Tin	231-141-8	7440-31-5	≤0.00005% (0.5ppm)
Selenium	231-957-4	7782-49-2	≤0.0002% (2.0ppm)
Zinc (soluble)	231-175-3	7440-66-6	≤0.2% (2000ppm)

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*
Acenaphthene	201-469-6	83-32-9	≤0.00005% (0.5ppm)
Acenaphthylene	201-469-6	83-32-9	≤0.00005% (0.5ppm)
Anthracene	204-371-1	120-12-7	≤0.00005% (0.5ppm)
Benz[a]anthracene	200-280-6	56-55-3	≤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[ghi]perylene	205-883-8	191-24-2	≤0.00005% (0.5ppm)
Benzo[a]pyrene	200-028-5	50-32-8	≤0.0000005% (0.005ppm)
Benzo[e]pyrene	205-892-7	192-97-2	≤0.00005% (0.5ppm)
Chrysene	205-923-4	218-01-9	≤0.00005% (0.5ppm)
Dibenz[a,h]anthracene	200-181-8	53-70-3	≤0.00005% (0.5ppm)
Fluoranthene	205-912-4	206-44-0	≤0.00005% (0.5ppm)

Fluorene	201-695-5	86-73-7	≤0.00005% (0.5ppm)
Indeno[1,2,3-cd]pyrene	205-893-2	193-39-5	≤0.00005% (0.5ppm)
Naphthalene	202-049-5	91-20-3	≤0.00005% (0.5ppm)
Phenanthrene	201-581-5	85-01-8	≤0.00005% (0.5ppm)
Pyrene	204-927-3	129-00-0	≤0.00005% (0.5ppm)

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.

EtalonMix 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). EtalonMix 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 'ETALONMIX' LLC



Michael Brown X

uality & Safety Manager