

Product Safety Data Sheet

1 - General Product View

Product trade name	ARTLINER® inks for PERMANENT MAKE-UP
Introduction	<p>ArtLiner® offers top premium quality micropigments to obtain the most natural permanent makeup effects. Unique formulation of organic and inorganic components provides almost total protection from herpes and allergenic reactions, protects health and supports healing.</p> <ul style="list-style-type: none"> ✓ All inks stay germfree if they are handled according to manufacturers recommendations ✓ All inks are manufactured in accordance with ResAP(2008)1 ✓ All inks are free of viable organisms including viruses – they are sterile (it means the absence of viable organisms, including viruses) ✓ All inks of every production contains Certificate of Analysis (CoA) for heavy metals with toxicological statement in accordance with CoE ResAP(2008)1 on tattoos and permanent make-up.
Route of Administration	Semi-tattooing procedures provided with electronic devices and disposable needle cartridges.
Active substances <u>excluded</u> from all inks (INCI)	<ul style="list-style-type: none"> • Without iron oxides • Without animal derivates • Without alcohol denat. • Without preservatives • Without acrylic • Without jojoba • Without rosin • Without bee derivates (e.g. propolis, honey, waxes) • Without formaldehyde donors (e.g.: DMDM Hydantoin, Diazolidinyl Urea, Imidazolidinyl Urea, Methenamine, Quaternium-15, Sodium Hydroxymethylglycinate)
Container (enclosure system)	PP bottles with security membrane. Sterile.
Capacity	3ml, 10ml
Shelf life period:	5 years from production date in original closed container
Shelf life (after first opening container)	1 year
Quality benefits	<p>Faster work for the operator and faster healing for patient Full compliance with skin and stability of colours against changes Absence of pigment green Intense saturation and longer durability Practically no risk of allergies No dilution needed Stability, saturation, durability: 24 months in-vivo tests (on live patients) in a direct route of administration (microblading) before market launch set done (launch: June 2019)</p>
Adequate marketing claims	<p><input checked="" type="checkbox"/> Sterile <input checked="" type="checkbox"/> Vegan friendly <input checked="" type="checkbox"/> Cruelty free (no animal tests) <input checked="" type="checkbox"/> Compliance with ResAP(2008)1</p>

2 - Composition

INCI	CAS	EINECS	PRESENCE / INK NUMBER
Propylene Glycol	57-55-6	200-338-0	101, 101-S, 102, 201-210, 301-310, 407
Glycerin (vegetable)	56-81-5	200-289-5	101, 101-S, 102, 201-210, 301-306, 308-310, 407
Hamamelis Virginiana Bark/Leaf Extract (vegetable)	84696-19-5	283-637-9	101, 101-S, 102, 201-210, 301-310, 407
Sodium Sulfate	7757-82-6	231-820-9	102, 202-210, 301-303, 305, 308-310, 407
Isopropyl alcohol	67-63-0	200-661-7	101, 101-S, 102, 201-210, 301-310, 407
PEG-40 Hydrogenated Castor Oil (vegetable)	61788-85-0	n/a	101, 102, 201-210, 301-310, 407
PVP	9003-39-8	n/a	101-S
CI 11767 (Pigment Yellow 97)	12225-18-2	235-427-3	102, 201-203, 205-210, 305, 309, 310, 407
CI 561170 (Pigment Orange 73)	84632-59-7	416-250-2	102, 203, 204, 207, 306, 308, 310, 407
CI 56110 (Pigment Red 254)	84632-65-5	n/a	210, 301-310, 407
CI 561300 (Pigment Red 264)	88949-33-1	413-920-6	102, 201-209, 301-306, 308, 309
CI 51345 (Pigment Violet 37)	57971-97-5/17741-63-8	n/a	302-304, 308-310
CI 77891 (Pigment White 6)	13463-67-7	236-675-5	102, 202-210, 301-303, 305, 308-310, 407
CI 77268:1 (Pigment Vegetable Charcoal)	1339-82-8	215-669-6	101, 102, 201-210, 303-304, 308-310, 407
CI 74160 (Pigment Blue)	147-14-8	205-685-1	102, 204
CI 77266 (Pigment Carbon Black)	1333-86-4	215-609-9	101-S

Product Safety Data Sheet

Page 2 of 4

3 - Manufacturer

Marketing Authorization Holder (Name Address & Country)	BEAUTY INTERNATIONAL - pl. Wolnica 13/10, 31-060 Cracow, Poland, EU tel.: +48 12 345 28 49, info@artliner.eu , www.artliner.eu
Number and Date of the first Marketing Authorization / Renewal	May 2019 (101, 101-S, 102, 201-210) June 2019 (301-310, 407)
Manufacturer of Finished Product (Name Address & Country)	BEAUTY INTERNATIONAL - pl. Wolnica 13/10, 31-060 Cracow, Poland, EU tel.: +48 12 345 28 49, info@artliner.eu , www.artliner.eu

4 - Hazards identification

Slight irritating to the eye balls.

5 - First – aid measures

Inhalation. If adverse effects occur, remove to uncontaminated area. If irritation persists obtain medical attention.
Skin. Patch test required before all procedures. Remove with tepid water and soap. If irritation persists obtain medical attention.
Eyes. Irrigate thoroughly with water for at least 15 minutes. Obtain medical attention if necessary.
Ingestion. Wash out mouth with water and give plenty of water to drink. Do not induce vomiting. Obtain medical attention if necessary.

6 - Fire – fighting measures

Suitable extinguishing media: not applicable
Unsuitable extinguishing media: not applicable
Additional information: not applicable
Special Hazards: none (not inflammable and not explosive product)

7 - Accidental Release Measures

Personal precautions: do not eat or drink when working, wash hands before breaks and after work.

Environmental precautions: do not allow to enter drains or water courses. Avoid subsoil penetration.

8 - Handling and Storage

Information for safe handling

Use normal standards of industrial hygiene for handling chemicals. Avoid contact with eyeballs.
 Store in a shaded place with ambient temperature (5-35°C). Keep container tightly closed when it is not in use.
 Keep away from direct sunlight and sources of UV radiation. Do not freeze. Do not use after defrosting.
 Do not keep in cartons foiled with stretch foil

Storage conditions

Store in a shaded place with ambient temperature (5-35°C). Keep container tightly closed when it is not in use.
 Keep away from direct sunlight and sources of UV radiation.
 Do not freeze. Do not use after defrosting.
 Do not keep in cartons foiled with stretch foil.

Information about protection against explosions and fires: without (not inflammable and not explosive product)

Further information about storage conditions: without

9 - Exposure Controls and Personal Protection

Components with critical values that require monitoring at the workplace (exposure limits): without

Personal protective equipment: not applicable / not required

General protective and hygiene measures: use normal standards of industrial hygiene for handling chemicals.
 Keep container tightly closed when not in use. Do not eat or drink when working, wash hands before breaks and after work.

Respiratory protection: not applicable / not required

Hand protection: not applicable / not required

Eye Protection: not applicable / not required

Body Protection: not applicable / not required

Product Safety Data Sheet

Page 3 of 4

10 - Physical and chemical properties

Form/texture: water based gel emulsion
Colour: various
Odour: odourless (no fragrance)
PH Value:
Molecule size:
Stability in skin: minimum 2 years dependant on skin condition and exposure to harmful external factors
Removal procedures: by picosecond laser type (if demanded)

Relevant safety date: 5 years since production date
Boiling point / rang: not applicable / not required
Vapor pressure: not applicable / not required
Density: not applicable / not required
Solvent – separation test: not applicable / not required
Solubility in water: soluble
Flow time: not applicable / not required
Viscosity: not applicable / not required

11 - Stability and reactivity

Conditions to avoid
High temperatures (>35°C), low temperatures (< -5°C), direct sunlight or UV sources, storage in cartons foiled with stretch foil.

Materials to avoid: oxidizing agents.

12 - Toxicological information

Products fulfil all toxicological demands of Council of Europe resolution 2008 [ResAP(2008)1] on tattoos and permanent make-up. This is considered as non toxic, non corrosive, non irritating, non phototoxic, non sensitisation, non photosensitisation and non genotoxic according to the Council of Europe Resolution [ResAP(2008)1] and today's knowledge.

13 - Ecological information

Details on elimination (persistence / degradability)
Do not discharge into drains or water courses. Avoid ground contamination.
Product is allow to enter waste water canal without diluting.
Methods for cleaning up: absorb with absorbent material (e.g. paper towel), place in suitable container and dispose of in accordance with national/local regulations relating to waste disposal.

Additional ecological information: without - no data is currently available.
Additional ecological data: without - no data is currently available.
Specification: without - no data is currently available.
Value / dosage: without - no data is currently available.

14 - Disposal considerations

Waste product must be disposed of in accordance with national/local legislative requirements.
Container disposal as for waste product disposal.

15 - Side effects

No adverse health effects have been observed or have been come to our knowledge if proper use is provided.

16 - Regulatory information

Classification according to EEC directives
Borderline product

Danger symbol and danger designation
Product does not require a hazard warning label in accordance with EC directives or regulations concerning dangerous substances.

Hazard – determining components of labelling
Product does not require a hazard warning label in accordance with EC directives or regulations concerning dangerous substances.

Product Safety Data Sheet

Page 4 of 4

Risk – Phrases

Product does not require a hazard warning label in accordance with EC directives or regulations concerning dangerous substances.

Safety – Phrases

Product does not require a hazard warning label in accordance with EC directives or regulations concerning dangerous substances.

National regulatory information

Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up.
Medical Device Directive 93/42/EEC for sterilisation procedures.

Regulation on inflammable liquids: not applicable / no data is currently available.

Emission control act: not applicable / no data is currently available.

Water pollution classification: not applicable / No data is currently available.

17 - Other information

Further information: all information targeted to the customers are located on the label of the product. There are no additional flyers inside the product.

R-phrases of components: without

This is to certify that the information contained herein is true and correct.

Name and title of responsible official in the company: **SYLWIA MICHNO – CEO/Founder.**

Notice: Information contained in this data sheet is based on current knowledge and usage, customers should satisfy themselves as to the suitability of this product for their own particular use.

This information is offered in good faith. Each user of this product needs to evaluate individual conditions of use (including the appropriate beauty procedures) to prevent from damages of patient's skin and/or negative side effects.

All detailed instructions that refer to the manual of permanent makeup procedures (pre- and after-care) are obtained during professional training locally by Authorised Trainer of ArtLiner® brand.

Beauty International, the legal owner of ArtLiner® brand assumed no responsibility for injury to the recipient or third parties, or for any health damage to any person resulting from misuse of the product without professional training confirmed by Competency Certificate.

ArtLiner® is a registered Trade Mark of Beauty International company.

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