



Sede legale:
via Vincenzo Monti 8 - 20123 - Milano - Italia
Sede Amministrativa ed Operativa:
via Nuova 1085/B - 35040 - Casale DI Scodosia (PD)
Tel: 0429/870076
e-mail: info@abcink.it
www.abcink.it
P.I. 10131850967 - C.F. 10131850967

PRODUCT SAFETY INFORMATION DATA SHEET

Created July 18, 2023

Last revised on 18 July 2023
Version: 01.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trading name:	POLYBIUS INK MEDIUM - LEVEL 2
Product type:	Mixture for tattoos or permanent makeup
REACH registration number:	Unnecessary.

1.2 Relevant identified uses of the substance or mixture and uses advised against:

1.2.1 Uses identified as relevant:

Mixture for tattoos or permanent makeup.

Ink to be used for permanent tattoos.

Professional use by qualified personnel, in possession of the requirements required by current laws, in suitable environments and in compliance with the most stringent hygiene and health standards.

1.2.2 Uses advised against:

The product should NOT be used in the eye area.

Uses other than those identified as relevant.

Other indications relating to how to use the product are available in section 16 of this document.

1.3 Information about the supplier of the safety data sheet

ABC INK SRL
Via Vincenzo Monti, 8
20123 – Milan (ITALY)
+39 0429 870076
info@abcink.it

1.4 Emergency telephone number

Responsible territorial bodies referred to in art. 45 of Regulation (EC) 1272/2008

ITALIAN MINISTRY OF HEALTH:

General Directorate of Medical Devices, Pharmaceutical Service and Care Safety - Office VII

Dr. Emanuela Fabbri +39 0659943733 - Dr. Daniela Gigante +39 0659943849

Main poison control centers:

- ROME: CAV Policlinico "A. Gemini" - Tel. +39 06.305.4343
- NAPLES: CAV "A. Cardarelli Hospital Company" - Tel. +39 081.545.3333
- VERONA: CAV Veneto Poison Control Center - Tel. 800.011.858



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SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

This product does not meet the criteria for classification in any hazard class in accordance with Regulation (EC) No. 1272/2008 relating to the classification, labeling and packaging of substances and mixtures. However, this sheet was created on a voluntary basis.

2.2 Label elements

Hazard pictograms:	--
Warnings:	Contains Nickel. May cause allergic reaction.
Hazard Statements:	--
Precautionary advice:	If you consult a doctor, keep the container or available the product label. Keep out of reach of children. Read the label before use. Obtain instructions before use. Do not handle until you have read and understood all warnings. Keep away from heat sources. Keep container tightly closed. Store only in the original container. Keep in a cool place. Protect from sunlight. Store in a dry place. Do not eat, drink or smoke when using. Do not dispose of in the environment. In case of malaise consult a doctor. <i>More information can be found in section 7.</i>

2.3 Other dangers

Based on available data, the product does not contain PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative) substances in a percentage greater than 0.1%.



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SECTION 3: Composition/information on ingredients

3.2 Substances

Not applicable.

3.2 Mixtures

The product does not contain substances classified as dangerous for health or the environment pursuant to the provisions of Regulation (EU) 1272/2008 (CLP) (and subsequent amendments and adjustments) in quantities that require declaration.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes:

It is highly unlikely that a reaction would occur that would require medical attention. If necessary, contact a doctor or poison control center and show this safety information sheet.

If inhaled:

Unlikely event as the product has a high concentration of non-volatiles. If irritation or other symptoms occur, go outdoors. Consult a doctor if irritation persists.

In contact with skin:

Contact is necessary for the function of the product. In case of accidental contact, wash thoroughly with soap and water. Take off contaminated clothing and wash it before wearing it again. In case of skin irritation contact a doctor.

In contact with eyes:

Rinse thoroughly for 15 minutes under running water, keeping the eyelids open. Remove any contact lenses. If in doubt, contact a doctor and show this safety information sheet.

If ingested:

If the person is conscious, rinse the mouth and drink plenty of water. Do not administer anything orally if the subject is unconscious and if you are not authorized by the doctor. If in doubt, contact a doctor or poison control center and show this safety information sheet. Induce vomiting only when advised by your doctor. In case of vomiting, keep your head down to avoid suffocation.

First responder self-protection:

The use of personal protective equipment is recommended to safeguard hygiene and safety.

4.2 Most important symptoms and effects, both acute and delayed

No known symptoms and dangerous effects.

4.3 Indication of any immediate medical attention and special treatment needed

No special recommendations. It is advisable, if necessary, to show this safety information sheet to the Doctor.

SECTION 5: Fire fighting measures

The product is not combustible except in extreme conditions and after complete evaporation of the water



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contained.

5.1 Extinguishing media

Suitable extinguishing media: Water spray, dry powder, foam, carbon dioxide (CO₂).

Unsuitable extinguishing media: Direct water jets.

5.2 Special hazards arising from the substance or mixture

Possible development of toxic fumes. Avoid breathing combustion products.

5.3 Recommendations for fire extinguishers

Do not enter the fire area without adequate protection, use self-breathing and personal protective equipment. We recommend that you show this safety information sheet to your employees. No further recommendations are expected.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and procedures in case of emergency

For those not directly involved:

Use personal protective equipment to prevent contamination of skin, eyes and personal clothing, more information in section 8.

Remove sources of ignition and heat, provide adequate ventilation.

For those directly involved:

Use personal protective equipment to prevent contamination of skin, eyes and personal clothing, more information in section 8.

Remove sources of ignition and heat, provide adequate ventilation.

6.2 Environmental precautions

Do not dispose of in the environment. Keep pure product away from drains, surface water and groundwater. Prevent the product from entering the water and sewage system. If significant quantities of product are lost, immediately notify the competent local authorities.

6.3 Methods and materials for containment and cleanup

Dry with absorbent material (e.g. cloth, tea towel), wash carefully with water and detergent, rinse. Avoid spillage into sewers. Dispose of the material used for containment and any residues in an authorized center.

6.4 Reference to other sections

Sections 8 and 13 of this safety information sheet.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Keep away from sources of light and heat. Shake the bottle before each use. Close immediately after use, keep product uncontaminated. Indicate, on the bottle or in a specific register, the date the product was first opened. Check that the product has not expired (based on the expiry date shown on the product label) and that it has not been opened for more than 6 (six) months. Do not mix the product with inks from other brands or with incompatible substances and mixtures. Do not eat, drink or smoke when using. For reasons



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hygienic and respectful towards the end customer, use disposable and sterile materials, in compliance with the most stringent hygiene and health standards.

7.2 Conditions for safe storage, including any incompatibilities

Store only in the original bottle. Keep uncontaminated, reseal immediately after use. Store tightly capped in a cool, dry place away from strong sources of light and heat, especially direct ones. Optimal temperatures for stability from +5°C to +25°C, avoid freezing. Periodically check the expiry date indicated on the label, do not use after this date. Do not mix or contaminate with incompatible chemicals. Store only in the original container.

7.3 Specific end uses

Mixture for tattoos for exclusive professional use by qualified personnel, in possession of the requirements required by current laws, in suitable environments and in compliance with the most stringent hygiene and health standards.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No further information available.

8.2 Exposure controls

Direct contact with the product is necessary for its function (see point 1.2 relating to uses identified as relevant). The following protective measures are designed to minimize any risks.

8.2.1 Suitable technical controls

Ensure adequate and sufficient ventilation. Follow the instructions for handling and storage in section 7 of this document.

8.2.2 Individual protection measures, such as personal protective equipment

Personal Protective Equipment Symbols:



a) Eye/face protection:

Use appropriate protective glasses to prevent product splashes from coming into contact with your eyes.

b) Skin/body protection (hand protection):

Not required, contact is necessary for the function of the product. The operator, for hygienic and health reasons, must use suitable disposable gloves, disposable gowns (suitable protective clothing) and any other personal protective equipment and precautions necessary to guarantee the hygiene and safety of the subject undergoing treatment.

c) Respiratory protection:

Ensure sufficient ventilation and ventilation. The operator, for hygienic and health reasons, must use a special disposable mask.

d) Thermal hazards:

No further information available.

8.2.3 Environmental exposure controls



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Do not dispose of in the environment. You can refer to what is reported in section 6 of this document.

SECTION 9: Physical and chemical properties

Mixture of pigments in water, stabilizing and wetting additives. The product kept in the original sealed container is chemically and microbiologically stable.

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Black
Odour:	Characteristic
Melting point/freezing point:	--
Initial boiling point: Flammability:	--
Upper/lower explosive limits:	--
Upper/lower flammability limits:	--
Flash point: Auto-ignition temperature:	--
Decomposition temperature:	> 80 °C
pH: Kinematic viscosity:	--
Solubility: Liquid soluble in water:	7.5 – 8.5
Insoluble pigments:	--
Partition coefficient: n-octanol/water:	--
Vapor pressure:	--
Relative density:	--
Relative vapor density:	--
Boiling range: Evaporation rate:	--
Explosive properties:	--
Oxidizing properties:	Non-explosive product
	--

9.2 Other information

No further information available.

SECTION 10: Stability and reactivity

10.1 Responsiveness

The product is non-reactive under normal conditions of use, storage and transportation. No dangerous reaction is expected if the requirements/instructions for storage and handling are respected (section 7 of this safety information sheet). Do not mix with products of other brands and products with relevant identified uses different from those described in this sheet.

10.2 Chemical stability

No dangerous reactions known if the requirements/indications for storage and handling are respected (section 7 of this safety information sheet). Do not mix with products of other brands and products with relevant identified uses different from those described in this sheet.

10.3 Possibility of hazardous reactions

No dangerous reactions known or expected if handled and stored as directed.



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10.4 Conditions to avoid

Please see section 7.2 of this safety information sheet.

10.5 Incompatible materials

Strong oxidants such as concentrated nitric acid, potassium dichromate in acidic solution, hydrogen peroxide at a concentration greater than 30% and similar.

10.6 Hazardous decomposition products

No dangerous decomposition products expected if the storage and handling requirements are respected as indicated in this sheet.

SECTION 11: Toxicological information

11.1 Information on the hazard classes defined in Regulation (EC) No. 1272/2008

Acute toxicity:	--
Skin corrosion/skin irritation:	--
Serious eye damage/eye irritation:	--
Respiratory or skin sensitization:	--
Germ cell mutagenicity:	--
Carcinogenicity:	--
Reproductive toxicity:	--
Specific target organ toxicity (STOT) – single exposure:	--
Specific target organ toxicity (STOT) – repeated exposure:	--
Aspiration Hazard:	--

The safety margin of the product is very high, so if used correctly, no particular reactions are to be expected beyond trauma to the tattoo.

11.2 Information on other hazards

No further information available

SECTION 12: Ecological information

12.1 Toxicity

No environmental hazards from the product are expected.

Glycerin:

- LC50 fish 1: 54000 mg/l (96 h, salmo gairdneri/oncorhynchus mykiss);
- LC50 other aquatic organisms 1: > 1000 mg/l (96 h);
- EC50 other aquatic organisms 1: > 1000 mg/l (activated sludge bacteria);
- LC50 fish 2: > 1000 mg/l (96 h, PISCES);
- EC50 Daphnia 2: > 10000 mg/l (24 h, daphnia magna movement);
- TLM fish 1: > 1000 ppm (96 h, PISCES);
- TLM other aquatic organisms 1: > 1000 ppm (96 h);
- Toxicity threshold of other aquatic organisms 1: 2900 mg/l (192 h, MICROCYSTIS AERUGINOSA, TOXICITY TEST)
- Toxicity threshold of other aquatic organisms 2: > 10000 mg/l (16 h, PSEUDOMONAS PUTIDA, TOXICITY TEST)
- Algae toxicity threshold 1: > 10000 mg/l (168 h, SCENEDESMUS QUADRICAUDA, TOXICITY TEST).
- LC50 - Fish > 100 mg/l/96h Trout - Oncorhynchus mykiss
- EC50 - Algae / Aquatic Plants > 3000 mg/l/72h Algae



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Isopropyl Alcohol:

Acute LC50 1400000 to 1950000 ug/L Sea water – Crustaceans – Cragon cragon (48 hours);
Acute LC50 > 1400000 ug/L – Fish – Gambuisa affinis – 20 to 30 mm (96 hours);

12.2 Persistence and degradability

No data available regarding the product.

Glycerin:

Biochemical oxygen demand BOD --> 0.87 g O₂/g matter
Chemical oxygen demand (COD) --> 1.16 g O₂/g matter (ISO 15705)
ThOD: 1.217 g O₂/g matter;
DBO (ThOD): 71% ThOD.

Rapidly degradable.

12.3 Bioaccumulative potential

Not expected for the product. Significant bioaccumulation is unlikely due to the general insolubility of the solid components. An accumulation of water-soluble components is unlikely.

Glycerin:

Log Pow: -1.76/2.6

Isopropyl Alcohol:

Log Pow: 0.05

12.4 Mobility in soil

The liquid phase of the product is soluble in water, the solid phase is insoluble and sediments in static systems.

Glycerin:

Surface tension: 0.063 N/m (20°C)
Ecology and soil: Biodegradability data not available.

12.5 Results of PBT and vPvB assessment

According to Annex XIII of Regulation (EC)N. 1907/2006 concerning the registration, authorization and restriction of chemical substances (REACH): the product does not contain substances that satisfy the PBT criteria (Persistent Bioaccumulative Toxic) or the vPvB criteria (very persistent, very bioaccumulative).

12.6 Endocrine disrupting properties

No further information available.

12.7 Other adverse effects

Not known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of the pure product as special waste, according to local and national regulations. Avoid disposal in the sewer system. Follow the recycling instructions of your municipality.
Do not reuse empty containers.



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Although all the components of the mixture are biodegradable or inert towards the environment, care must be taken to dispose of containers and any product residues according to applicable local, national and supranational regulations.

SECTION 14: Transport information

In compliance with: ADR / IMDG / IATA / ADN / RID

14.1 UN number or ID number

Not regulated as a dangerous product.

14.2 UN proper shipping name

Not regulated as a dangerous product.

14.3 Transport hazard classes

Not regulated as a dangerous product.

14.4 Packing group

Not regulated as a dangerous product.

14.5 Dangers for the environment

Not regulated as a dangerous product.

14.6 Special precautions for users

Ground transportation:	--
Sea transport:	--
Airplane transport:	--
River transport:	--
Transport by rail:	--

14.7 Maritime transport in bulk in accordance with IMO acts

Not applicable.

SECTION 15: Regulatory information

15.1 Health, safety and environmental laws and regulations specific to the substance or mixture

Regulation (EC) 1907/2006 (REACH) of the European Parliament and of the Council of 18 December 2006 and all amendments and modifications.

Commission Regulation (EU) 2020/2081 of 14 December 2020 amending Annex XVII to Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH) with regard to substances contained in tattoo inks or permanent make-up.

Regulation (EC) no. 1272/2008 (CLP) of the European Parliament and of the Council of 16 December 2008 and all amendments and modifications.



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ResAp(2008)1: the Council of Europe resolution on the requirements and criteria for the safety of tattoos and permanent make-up and references therein.

15.2 Chemical safety assessment

The safety margin of the product is very high, so if used correctly, no particular reactions are to be expected beyond trauma to the tattoo. Considering this product to be non-hazardous, no chemical safety assessment has been conducted for this mixture by the supplier.

SECTION 16: Other information

16.1 Method of use

Professional use.
Shake the bottle well before use.
We recommend compliance with the most stringent hygiene and health standards when using the product.
Do not operate on damaged skin.
Clean the area to be treated thoroughly.
For subjects predisposed to intolerance reactions, a preventive allergy test is advisable.
Do not use in case of positive response.
Do not apply on irritated or inflamed skin.

16.2 Information on the mixture

Contains Nickel. May cause allergic reactions.
Carry out a preventive allergy test.
Consult your doctor before proceeding with treatments on allergy-positive subjects.

16.3 Operators

Product intended for use exclusively by personnel with the necessary qualifications required by local and national regulations for carrying out tattoo and semi-permanent make-up treatments.
The treatments must take place in suitable facilities, in compliance with local and national regulations.
Before use, it is necessary to provide the person undergoing tattooing with the information on the packaging as well as that in this product safety information sheet.

16.4 Information on the label

Product name.
Wording "Tattoo mixture"
Unique reference number for lot identification [LOT].
Optimal temperature for stability.
Product expiry date.
List of ingredients in INCI nomenclature.
Indication of the PH regulator.
Wording "Contains Nickel. May cause allergic reactions."
Instructions for use and storage.
Validity after opening the product.
Bottle capacity.
Disposal information.
Name of the person responsible for placing it on the market.



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16.5 Abbreviations and acronyms

CAV	Poison Control Center
PBT	Persistent, bioaccumulative and toxic substance vPvB
	Very persistent and very bioaccumulative
LC50	Lethal concentration 50%
LD50	Median lethal dose that causes the death of 50% of the individuals tested
TLM	Median tolerance limit
BOD	Biochemical oxygen demand
COD	Chemical oxygen demand
ThOD	Theoretical oxygen demand
ADR	European agreement on the international transport of dangerous goods by road
IMDG	International Maritime Dangerous Goods Code
IATA	International Air Transport Association
ADN	European Agreement on the International Carriage of Dangerous Goods on Inland Waterways
RID	Regulations on the international transport of dangerous goods by rail

This sheet was created on a voluntary basis.
A safety data sheet is not required for this product.

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