

Safety Data Sheet

according to Regulation (EC) no. 1907/2006 (REACH) as amended by Regulation (EU) 2020/878

Issue date: 01/05/2025 - Version: 1.0

PROHERN WHITE INK

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

1.1 PRODUCT IDENTIFIER

Product name: Prohern White Ink

Product description: Mixture for tattooing – Tattoo ink, white colour

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Use of the substance/preparation:

Product intended for professional use as tattoo ink.

Uses advised against:

Do not tattoo eyeballs and do not ingest

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Produced by Cosmesis s.r.l. - via Albignano no.19, 24040 Casirate D'Adda (BG) Italy, for Prohern Mateusz Przysucha address Rynkowa 31 Michałowice , Vat ID PL5342638932

E-mail: bigboss@prohern.com

Tel.: +48509267575

1.4 EMERGENCY TELEPHONE NUMBER

Emergency telephone number for the European Union: **112**

Other EU centres opened 24hrs for poisoning emergencies:

Anti-poison centres and Hospitals	Address	Emergency telephone number/contacts
Centro Antiveleni di Milano - ASST Grande Ospedale Metropolitano Niguarda (Niguarda Metropolitan Hospital)	Piazza dell'Ospedale Maggiore, 3, 20161 Milan - Italy	+39 02 66101029
Centre antipoison et de toxicovigilance de Paris - Hôpital Fernand Widal (Fernand Widal Hospital)	Rue du Faubourg, 200, St Denis 75010 Paris - France	+33 (0)1 40 05 48 48
National Poisons Information Centre - University Medical Centre Utrecht	Postbus 85500 3508 GA Utrecht - Netherlands	+31 (0)30 274 88 88
Giftnotruf München - Toxikologische Abteilung der II Medizinischen Klinik rechts der Isar der TU	Ismaninger Strasse, 22, 81675 Munich - Germany	+49 (0)89 192 40
Servicio de Información Toxicológica - Instituto Nacional de Toxicología y Ciencias Forenses	Echegaray n° 4 Las Rozas 28232 Madrid - Spain	+34 91 562 0420

SECTION 2: Hazards identification

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According to the available information, the product is not dangerous for humans and the environment under correct conditions of use. However, the possibility of an allergic reaction in particularly sensitive individuals cannot be excluded. Do not ingest the product; its use in the eye area is not recommended.

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to Regulation (EC) no. 1272/2008 (CLP):

Not classified

Adverse physicochemical, human health and environmental effects:

According to the information available, the product does not present any particular risks, subject to compliance with the general rules of industrial hygiene.

2.2 LABEL ELEMENTS

Labelling according to Regulation (EC) no. 1272/2008

Not applicable

Hazard pictograms

Not applicable

Warning

Not applicable

Hazard statements

Not applicable

2.3 OTHER HAZARDS

The product does not contain PBT or vPvB substances in a percentage higher than 0.1% in compliance with the provisions of REACH Annex XIII.

SECTION 3: Composition/information on ingredients

3.1 SUBSTANCES

Not applicable

3.2 MIXTURES

Ingredients listed in descending order as required by current legislation:

Ingredient	CAS No.	Hazard classification according to Regulation (EC) no.1272/2008 (CLP)
Aqua	7732-18-5	
Titanium dioxide	13463-67-7	
Glycerin	56-81-5	Eye irritation H319
Polysorbate 80	9005-65-6	
Aroma	8001-25-0 / 504-63-2 / 8001-31-8 / 5343-92-0 / 84012-35-1	

Legend of abbreviations and dangers mentioned in section 16.

SECTION 4: First aid measures

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4.1 DESCRIPTION OF FIRST AID MEASURES

- **inhalation:** product with a high concentration of non-volatile substances, the event is therefore highly unlikely. If irritation or other symptoms occur, move to fresh air.
- **Skin contact:** contact with skin is necessary for normal use of the product. Based on the tests carried out, the product is generally not irritating to the skin. Consult a doctor if irritation occurs.
- **Eye contact:** Rinse the eye thoroughly under running water for a few minutes, keeping eyelids wide open. In case of pain or persistent irritation consult an eye specialist.
- **Ingestion:** Contact a doctor or a poison center. If person is conscious, rinse mouth and drink plenty of water. Do not administer anything and do not induce vomiting in case of unconsciousness or in the absence of medical authorisation.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS BOTH ACUTE AND DELAYED

No further information is available

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No further information is available. If necessary, it is recommended to show this safety data sheet.

SECTION 5: Firefighting measures

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media: water spray, dry powder, foam, carbon dioxide

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Avoid breathing combustion fumes. No further information is available

5.3 ADVICE FOR FIREFIGHTERS

Do not intervene without appropriate protective equipment.

SECTION 6: Accidental release measures

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Use personal protective equipment referred to in section 8. Ensure good ventilation of the place of release, if indoors.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid release to the environment. Prevent infiltration of the pure product into wastewater, surface water or groundwater.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Collect the liquid with absorbent material (e.g., cloth, sawdust, sand). Wash with water and detergent, rinse.

6.4 REFERENCE TO OTHER SECTIONS

For further information refer to sections 8 and 13.

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SECTION 7: Handling and Storage

7.1 PRECAUTIONS FOR SAFE HANDLING

For hygienic reasons and in compliance with health regulations, use the product with sterile and disposable materials. Shake the bottle before each use. Close the bottle immediately after use to keep the product uncontaminated. Periodically check the expiry date of the product and keep note of the date of first opening. Avoid eating, drinking or smoking during use.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep the product in the original bottle. Store in a cool, dry place, away from light and heat sources. Recommended storage temperature 5C° - 30C°. Avoid freezing.

7.3 SPECIFIC END USES

Product intended for professional use, by qualified personnel, in possession of the legal requirements in force and in compliance with hygiene and health standards.

SECTION 8: Exposure controls / personal protection

8.1 CONTROL PARAMETERS

Predicted No-Effect Concentrations (PNEC)

- Glycerin

- Danger to aquatic organisms
 - Freshwater: No hazards identified
 - Sea water: No hazards identified
- Sewage Treatment Plant (STP) 1 g/L
 - Sediment (Freshwater): No hazards identified
 - Sediment (Sea water): No hazards identified
- Danger for terrestrial organisms: No hazards identified
- Air hazard: No hazards identified
- Danger to predators - Secondary poisoning: No bioaccumulation potential.

Derived No-Effect Level (DNEL)

Data for workers

INHALATION		
Exposure	Exposure threshold	More sensitive study
Systemic effect		
Long-term	No hazards identified	-
Acute/short-term	No hazards identified	-
Local effects		

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Long-term	220 mg/m ³	irritation (respiratory tract)
Acute/short-term	No hazards identified	-
DERMAL		
Exposure	Exposure threshold	More sensitive study
Systemic effect		
Long-term	No hazards identified	-
Acute/short-term	No hazards identified	-
Local effects		
Long-term	No hazards identified	-
Acute/short-term	No hazards identified	-
EYES		
Exposure		
Low risk (no derived threshold)	No hazards identified	-

Data for general population

INHALATION		
Exposure	Exposure threshold	More sensitive study
Systemic effect		
Long-term	No hazards identified	-
Acute/short-term	No hazards identified	-
Local effects		
Long-term	132 mg/m ³	irritation (respiratory tract)
Acute/short-term	No hazards identified	-
DERMAL		
Exposure	Exposure threshold	More sensitive study
Systemic effect		
Long-term	No hazards identified	-
Acute/short-term	No hazards identified	-
Local effects		
Long-term	No hazards identified	-
Acute/short-term	No hazards identified	-
ORAL		
Exposure	Exposure threshold	More sensitive study
Systemic effect		
Long-term	No hazards identified	-
Acute/short-term	No hazards identified	-
EYES		
Exposure		
Low risk (no derived threshold)	No hazards identified	-

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8.2 EXPOSURE CONTROLS

Direct contact with the product is provided for its normal use (see point 1.2), for this reason no damage is expected in the event of exposure. The following protective measures are therefore intended to minimise any risk.

- Appropriate engineering controls: Ensure good ventilation in the workplace through an effective local aspiration. Individual protection measures must bear the CE marking which certifying their compliance with current regulations. Exposure levels should be kept as low as possible to avoid significant accumulation in the organism. Manage individual protection measures in such way as to ensure maximum protection (replace periodically and before deterioration). Please refer to point 7 above for further information;
- Individual protection measures (it is recommended to use only "CE" marked devices):
 - Eyes and face protection: Protective goggles to prevent splashes of product coming into contact with the eyes;
 - Skin protection: Not required. For hand protection, however, we recommend the use of disposable protective gloves suitable for handling the product due to their impermeability and stability.
 - Respiratory protection: Ensure sufficient ventilation and aeration in the place of the use. Furthermore, it is recommended to wear a mask.

SECTION 9: Physical and chemical properties

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	liquid
Colour:	white
Odour:	distinctive
Odour threshold	not available
pH:	6,3 – 6,5
Melting point/freezing point:	not available
Boiling point and boiling range:	not available
Flammability:	not available
Evaporation rate	not available
Vapour pressure:	not available
Vapour density:	not available
Relative density:	not available
Water solubility:	not available
Partitioning coefficient: n-octanol/water:	not available
Auto-ignition temperature:	not available
Decomposition temperature:	not available
Viscosity:	261 mPa*S
Explosive properties:	not available
Oxidative properties:	not available
Flammability/explosivity limits:	not available
Granulometry:	not available
Conductibility:	1657 μ s

9.2 OTHER INFORMATION

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No further information is available.

SECTION 10: Stability and reactivity

There are no particular dangers of reaction with other substances under normal conditions of use. The product is stable under normal conditions of use, temperature and pressure. Do not expose the product to extreme temperatures.

10.1 REACTIVITY

Based on available data, the product is non-reactive under normal conditions of use, storage and transport.

10.2 CHEMICAL STABILITY

The product is stable under normal conditions of use and storage.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No hazardous reactions known under normal conditions of use.

10.4 CONDITIONS TO AVOID

See section 7.2 of this Safety Data Sheet.

10.5 INCOMPATIBLE MATERIALS

No further information is available.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

No hazardous decomposition products if normal conditions of use and storage are observed.

SECTION 11: Toxicological informations

In the light of the available data, the product is particularly safe. In this sense, under conditions of normal use, no particular reactions are to be expected.

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity (oral):	Not classified
Acute toxicity (dermal):	Not classified
Acute toxicity (inhalation):	Not classified
Skin corrosion/ irritation:	Not classified – pH 6,3/6,5
Serious eye damage / irritation:	Not classified – pH 6,3/6,5
Respiratory or skin sensitisation:	Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Not classified
STOT– single exposure:	Not classified

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STOT – repeated exposure:

Not classified

Aspiration hazard:

Not classified

SECTION 12: Ecological informations

The product is generally not to be considered as hazardous for the environment and it does not cause any undesirable long-term effects.

TOXICITY

Glycerin:

- Fishes: LC50 (4 days) 54 g/L
- Short-term toxicity to aquatic invertebrates: EC50: 10 g/L – 24h

RESULTS OF PBT AND vPvB ASSESSMENT

According to the current chemicals legislation (i.e., REACH Regulation, Annex XIII), the product does not contain substances that fulfil the PBT and vPvB criteria.

OTHER ADVERSE EFFECTS

On the basis of available data, no other adverse effects are known.

SECTION 13: Disposal considerations

For the disposal of the product follow the administrative provisions of the country of residence.

SECTION 14: Transport information

The product is not classified as hazardous substance according to the current legislation, therefore any particular provisions on the transport of the hazardous good are not applicable within the UN.

Therefore, the provisions of the following regulations are not applicable: European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), Regulations concerning the International Transport of Dangerous Goods by Rail (RID), European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN), all three implemented by Directive 2008/68/EC of the European Parliament and of the Council of 24th September 2008, as well as International Maritime Dangerous Goods Code (IMDG – by sea) and Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO – by air). The provision for bulk transport under Annex II of MARPOL Agreement and the IBC Code of the International Maritime Organization (IMO) not apply either.

SECTION 15: Regulatory information

15.1 HEALTH AND ENVIRONMENTAL REGULATIONS OR LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

EU REGULATIONS:

Contains no REACH substances with Annex XVII restrictions. Contains no substance on the REACH candidate list. Contains no REACH Annex XIV substances. Contains no substances subject to (UE) Regulation no. 649/2012 of 4th July 2012 on export and import of hazardous chemical substances. Contains no substance

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subject to Regulation (EU) no. 2019/1021 of 20th June 2019 on persistent organic pollutants. Contains no substance subject to Regulation (EC) no. 1005/2009 of 16th September 2009 on substances that deplete the ozone layer. It does not contain any substance subject to Regulation (EU) 2019/1148 of 20th June 2019 on the marketing and use of explosives precursors.

Compliance with current regulations:

Regulation (EC) no. 1907/2006 of 18th December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) no. 793/93 and Commission Regulation (EC) no. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Commission Regulation (EU) 2020/2081 of 14th December 2020 amending Annex XVII to Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up, Official Journal of the European Union of 15th December 2020, L 423/6.

Commission Regulation (EU) 2015/830 of 28th May 2015 amending Regulation (EC) No 1907/2006.

It is not classified as hazardous according to Directives 67/548/EEC and/or 1999/45/EC. Regulation (EC) no. 1272/2008 on classification, labelling and packaging. Official Journal of the European Union of 27th July 2012, no. L 201/60. Classification according to EC 67/548 or EC 1999/45.

Contains no substances subject to Regulation (EC) no. 273/2004 of 11th February 2004 on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

NATIONAL REGULATIONS: No further information is available.

15.2 CHEMICAL SAFETY ASSESSMENT

No chemical safety assessment has been carried out.

SECTION 16: Other information

Disclaimer:

The data are reported on the basis of our current knowledge; however, they do not represent any guarantee of the characteristics of the product and describe the same for the purposes of health, safety and environmental requirements only. It should therefore not be interpreted as a guarantee of any specific property of the product. To the extent that the product referred to in this Safety Data Sheet is mixed, blended or processed with other materials and/or ingredients that are not expressly indicated as suitable by COSMOINK, the information referred to in this Safety Data Sheet cannot be transferred to the new product. This Safety Data Sheet does not exempt the end user from ensuring that she/he is acting in compliance with current regulations.

Abbreviations and acronyms:

BOD	Biochemical Oxygen Demand (BOD)
COD	Chemical Oxygen Demand (COD)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC number	EC number (European Community)
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer

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IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods Code
LC50	Median lethal concentration of individuals tested
LD50	Median lethal dose resulting in the death of 50% of individuals tested
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBTs	Persistent Bioaccumulative Toxic Substances
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Transport of Dangerous Goods by Rail
MSDS	Safety Data Sheet
STP	Sewage Treatment Plant
ThOD	Theoretical Oxygen Demand (ThOD)
TLM	Median Tolerance Limit
COV	Volatile Organic Compounds
Numero CAS	CAS Number (Chemical Abstract Service)
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

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