

SAFETY DATA SHEET

Prepared in accordance with the Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ of EU no L203 of 26 June 2020)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Maderm pigment - permanent make-up ink

(PMP-22 MADERM pigment Toffee, PMP-46 MADERM pigment Americana, PMP-19 MADERM pigment Muscat, PMP-34 MADERM pigment Black, PMP-04 MADERM pigment Arabica, PMP-26 MADERM pigment Hollywood Kiss, PMP-04 MADERM pigment Arabica, PMP-09 Mocca, PMP-55 MADERM pigment Rosaline, PMP-39 MADERM pigment Espresso, PMP-56 MADERM pigment Charmine Rose, PMP-38 MADERM pigment Red Wine, PMP-45 MADERM pigment Paloma, PMP-59 MADERM pigment Lip Light, PMP-51 MADERM pigment Golden Brown, PMP-03 MADERM pigment Dark Blond, PMP-21 MADERM pigment Cream Cherry, PMP-12 MADERM pigment Brasiliana, MMP-04 MADERM pigment Arabica microblading Ink, MMP-39 MADERM pigment Espresso microblading Ink; PMP-62 MADERM pigment Barbados, PMP-48 MADERM pigment Barbie Pink, PMP-32 MADERM pigment Nude, PMP-44 MADERM Orange)

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

Identified uses: Permanent makeup pigments.

Uses advised against: Not identified.

1.3 Details of the supplier of the safety data sheet:

Supplier:

Maderm Esthetic Agnieszka Cepińska-Majewska
23a, Żeromskiego Str.
63-400 Ostrów Wielkopolski, Poland
Phone: + 48 508 111 718

E-mail address of the person responsible for the SDS: manager@maderm.eu

1.4 Emergency telephone number

Emergency telephone number in Poland (operating Mo.-Fr. 10:00 – 18:00): + 48 508 111 718

Date of compilation/verification: 2019.12.05/2020/04.09 (1)/2023.03.08 (2)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

The product is not classified according to current rules.

Harmful effects on human health:

In case of direct contact with eyes may cause slight irritation, redness, tearing. Contact with skin may cause temporary redness, itching. Swallowing large amounts may cause nausea, vomiting, diarrhea.

Environmental effects:

With proper use does not pose risk to the environment.

Adverse effects associated with physico-chemical properties:

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Not identified.

2.2 Label elements

Pictograms: Not required.

Signal Word: Not required.

Hazard Statements: Not required.

Precautionary statements: Not required.

EUH210 - Safety data sheet available on request.

2.3 Other hazards

This mixture meets neither PBT nor vPvB criteria. It does not contain ingredients that are considered endocrine disruptors according to Art. 57 (f) of REACH Regulation or Regulation (EU) 2017/2100 or Regulation (EU) 2018/605 at a concentration of 0.1% or higher.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

Product identifier: *Maderm pigment - permanent make-up ink*

(PMP-22 MADERM pigment Toffee, PMP-46 MADERM pigment Americana, PMP-19 MADERM pigment Muscat, PMP-34 MADERM pigment Black, PMP-04 MADERM pigment Arabica, PMP-26 MADERM pigment Hollywood Kiss, PMP-04 MADERM pigment Arabica, PMP-09 Mocca, PMP-55 MADERM pigment Rosaline, PMP-39 MADERM pigment Espresso, PMP-56 MADERM pigment Charmine Rose, PMP-38 MADERM pigment Red Wine, PMP-45 MADERM pigment Paloma, PMP-59 MADERM pigment Lip Light, PMP-51 MADERM pigment Golden Brown, PMP-03 MADERM pigment Dark Blond, PMP-21 MADERM pigment Cream Cherry, PMP-12 MADERM pigment Brasiliana, MMP-04 MADERM pigment Arabica microblading Ink, MMP-39 MADERM pigment Espresso microblading Ink; PMP-62 MADERM pigment Barbados, PMP-48 MADERM pigment Barbie Pink, PMP-32 MADERM pigment Nude, PMP-44 MADERM Orange)

The mixture does not contain ingredients classified as hazardous according to Regulation 1272/2008 (CLP) with later amendments.

The product contains:

Glycerol (CAS: 56-81-5; EC: 200-289-5) – OEL values established

Propane-1,2-diol (CAS: 57-55-6; EC: 200-338-0) - OEL values established

Sodium calcium phosphosilicate (CAS: 94551-68-5; EC: 305-416-9)

PEG - 8 (CAS: 5117-19-1; WE: 225-856-4)

Witch hazel leaf extract

Emulsifier - Polysorbat 80

Dyes

and water.

All pigments meet the requirements for products used for tattoo and permanent make-up and pose no health risks. Pigments are certified for heavy metals, aromatic amines (<1 ppm), polycyclic aromatic hydrocarbons -PAH (<10 ppb), dyes (<5 ppm) and microbiological tests.

Explanation of abbreviations and acronyms have been specified in the Section 16 of this safety data sheet.

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

- | | |
|---------------|--|
| Inhalation: | Remove casualty from exposure site to fresh air, place in reclining or sitting position, keep at rest and protect against heat loss. If symptoms persist, obtain medical attention. |
| Skin contact: | Take off contaminated clothes and rinse immediately with plenty of water and soap. If necessary, consult a physician. |
| Eye contact: | Rinse immediately with plenty of lukewarm water for at least 15 min. Remove contact lenses. To avoid cornea damage, don't use jet stream. If irritation persists, seek ophthalmologist's advice. |
| Ingestion: | If swallowed, don't provoke vomiting. Rinse mouth with water, give the casualty plenty of water to drink (unless unconscious). Provide medical attention immediately. |

4.2 Most important symptoms and effects, both acute and delayed

In case of direct contact with eyes may cause slight irritation, redness, tearing. Contact with skin may cause temporary redness, itching. Swallowing large amounts may cause nausea, vomiting, diarrhea.

4.3 Indication of any immediate medical attention and special treatment needed

No special requirements. Apply symptomatic treatment.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Non-flammable mixture. Fire in the surroundings should be extinguished with the media suitable for the materials involved in fire. Containers exposed to fire should be cooled from a safe distance with water spray.

Unsuitable extinguishing media: Do not use a direct water-jet.

5.2 Special hazards arising from the substance or mixture

During fire carbon oxide, carbon dioxide and nitrogen oxides may be emitted.

5.3 Advice for firefighters

Wear gas-tight protective suit and life air support or self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing made of natural fabrics (cotton) or synthetic fibres, safety gloves made of nitrile (thickness 0.4 ± 0.05 mm, breakthrough time ≥ 480 min) and safety goggles. Remove from the affected area unprotected persons who do not participate in removal of the failure.

6.2 Environmental precautions

Protect from releasing to a sewage system, surface, ground water and soil.

6.3 Methods and materials for containment and cleaning up

Secure sink basins. Damaged packaging place in an overpack. Small amounts absorb into chemically inert binding material (sand, diatomaceous earth), transfer to tight containers and pass to disposal. Wash contaminated surface with plenty of water.

6.4 Reference to other sections

Remove according to the recommendations listed in the section 13.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Provide appropriate general ventilation. Protect from entering into drain system, surface, ground water and soil. Do not eat, drink or smoke while handling. Wash hands during intervals and after finishing work.

7.2 Conditions for safe storage, including any incompatibilities

Store in original, properly labelled, tightly closed containers; in a dry, cool, properly ventilated storage premise.

7.3 Specific end use(s)

No information about the applications other than those mentioned in subsection 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Controls parameters

Component	CAS No.	Parameter	Value	Unit
Propane-1,2-diol total vapour and particulates	57-55-6	WEL (8-hr TWA)	150 474	ppm mg/m ³
particulates		WEL (8-hr TWA)	10	mg/m ³
Glycerol, mist	56-81-5	WEL (8-hr TWA)	10	mg/m ³

[EH40/2005 Workplace exposure limits, Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended)]

8.2 Exposure controls

8.2.1 *Appropriate engineering controls*

Install proper general workplace ventilation.

8.2.2 *Individual protective measures such as personal protective equipment*

Respiratory protection: Not necessary under normal conditions.

Skin and hands protection: When handling large amounts, wear protective clothing made of natural fabrics (cotton) or synthetic fibres, safety gloves made of nitrile (thickness 0.4 ± 0.05 mm, breakthrough time ≥ 480 min).

Eye/face protection: Not required.

Occupational hygiene: General industrial hygiene rules apply. Don't allow exceeding occupational exposure levels. After finishing work remove contaminated clothes. Wash hands and face before work breaks. Wash entire body after finishing work. Do not drink, eat and smoke during work.

8.2.3 *Environmental exposure controls*

Prevent from draining to a municipal sewage system and watercourses.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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9.1 Information on basic physical and chemical properties

- a) Physical state
Liquid.
- b) Colour
Colour dependent on specifications.
- c) Odour
No data.
- d) Melting point/freezing point
No data.
- e) Boiling point or initial boiling point and boiling range
> 100 °C.
- f) Flammability
Non-flammable product.
- g) Lower and upper explosion limit
Not applicable. The mixture does not pose an explosion hazard.
- h) Flash point
Non-flammable product.
- i) Auto-ignition temperature
No data available.
- j) Decomposition temperature
No data available.
- k) pH
No data available.
- l) Kinematic viscosity
No data available.
- m) Solubility
No data available.
- n) Partition coefficient: n-octanol/water (log value)
No data available.
- o) Vapour pressure
No data available.
- p) Density and/or relative density
0.9 – 1,36 (water=1)
- q) Relative vapour density
No data available.
- r) Particle characteristics
Not applicable (liquid).

9.2 Other information

9.2.1 Information with regard to physical hazard classes

- a) Explosives: Not applicable
- b) Flammable gases: Not applicable
- c) Aerosols: Not applicable
- d) Oxidising gases: Not applicable
- e) Gases under pressure: Not applicable
- f) Flammable liquids: Not applicable
- g) Flammable solids: Not applicable
- h) Self-reactive substances and mixtures: Not applicable
- i) Pyrophoric liquids: Not applicable
- j) Pyrophoric solids: Not applicable
- k) Self-heating substances and mixtures: Not applicable
- l) Substances and mixtures, which emit flammable gases in contact with water: Not applicable
- m) Oxidising liquids: Not applicable
- n) Oxidising solids: Not applicable

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- o) Organic peroxides: Not applicable
- p) Corrosive to metals: Not applicable
- q) Desensitised explosive: Not applicable

9.2.2 Other safety characteristics

In contact with water, the hydrolytic decomposition occurs; ethanol is formed.

- a) mechanical sensitivity: No data available
- b) self-accelerating polymerisation temperature: No data available
- c) formation of explosible dust/air mixtures: Not applicable
- d) acid/alkaline reserve: No data available
- e) evaporation rate: No data available
- f) miscibility: No data available
- g) conductivity: No data available
- h) corrosiveness: No data available
- i) gas group: Not applicable
- j) redox potential: No data available
- k) radical formation potential: No data available
- l) photocatalytic properties: No data available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No reactivity if stored and used according to the identified uses.

10.2 Chemical stability

Stable in standard conditions of storage and use.

10.3 Possibility of hazardous reactions

None identified.

10.4 Conditions to avoid

None identified.

10.5 Incompatible materials

None identified.

10.6 Hazardous decomposition products

None identified.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity:

Based on available data, the classification criteria are not met.

<u>Component</u>	<u>CAS No.</u>	<u>Method</u>	<u>Value</u>	<u>Unit</u>
Glycerol	56-81-5	LD ₅₀ – oral, rat	12600	mg/kg
Propane-1,2-diol	57-55-6	LD ₅₀ – oral, rat	> 20000	mg/kg
		LC ₅₀ – inhalation, rabbit	317.042	mg/l
		LD ₅₀ – skin, rabbit	> 2000	mg/kg

Skin Irritation/Corrosivity :

Based on available data, the classification criteria are not met.

Serious eye damage/irritation :

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Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity – single exposure:

Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity – repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

It does not contain ingredients which are considered endocrine disruptors according to Art. 57 (f) of REACH or Regulation (EU) 2017/2100 or Regulation (EU) 2018/605 at a concentration of 0.1% or higher.

11.2.2 Other information

No data.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Based on available data, the classification criteria are not met.

<u>Component</u>	<u>CAS No.</u>	<u>Method</u>	<u>Value</u>	<u>Unit</u>
Glycerol	56-81-5	LC ₅₀ – fish (<i>Leuciscus idus</i>)	>10000	mg/l
		LC ₅₀ – fish (<i>Carassius auratus</i>)	>5000	mg/l (24h)
		EC ₅₀ – invertebrates (<i>Daphnia magna</i>)	>10000	mg/l (24h)
		EC ₅₀ – bacteria (<i>Pseudomonas putida</i>)	>10000	mg/l (16h)
Propane-1,2-diol	57-55-6	LC ₅₀ – fish (<i>Oncorhynchus mykiss</i>)	40613	mg/l (96h)
		LC ₅₀ – invertebrates (<i>Ceriodaphnia dubia</i>)	18340	mg/l (48h)
		LC ₅₀ – invertebrates (<i>Mysidopsis bahia</i>)	18800	mg/l (96h)
		EC ₅₀ – algae (<i>Selenastum capricornutum</i>)	19000	mg/l (96h)
		NOEC – invertebrates (<i>Ceriodaphnia</i>)	13020	mg/l (7 days)
		NOEC – bacteria (<i>Pseudomonas putida</i>)	>20000	mg/l (18h)

12.2 Persistence and degradability

Glycerol: readily biodegradable (> 60 % after 28 days – closed bottle test)

Propane-1,2-diol: readily biodegradable (81 % after 28 days – OECD 301F, 96 % after 64 days – OECD 306)

12.3 Bioaccumulative potential

Partition coefficient octanol/water: (K_{ow}): Not determined for the mixture.

Bioconcentration factor (BCF): Not determined for the mixture.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

The mixture meets neither PBT nor vPvB criteria.

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12.6 Endocrine disrupting properties

The mixture does not contain ingredients that are considered endocrine disruptors according to Art. 57 (f) of REACH Regulation or Regulation (EU) 2017/2100 or Regulation (EU) 2018/605 at a concentration of 0.1% or higher.

12.7 Other adverse effects

No data.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Do not dispose together with municipal waste. Do not allow contamination of watercourses.
Used packaging, should be thoroughly emptied. Re-use package can be (after cleaning) reused. Single-use container (after thorough cleaning) shall be recycled.

Special precautions:

No special precautions.

SECTION 14: TRANSPORT INFORMATION

ADR/RID, IMDG, IATA

14.1 UN number or ID number

Not applicable.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

The product is not hazardous for the environment according to the model UN criteria.

14.6 Special precautions for user

No special precautions.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: REGULATORY INFORMATION

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a 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 (OJ EU L396 of December 30, with later amendments);

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REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ EU L353 of December, 31 2008, with later amendments ATP 1-18).

15.2 Chemical safety assessment

Supplier has not assessed the chemical safety of the mixture (mixture does not pose a risk).

SECTION 16: OTHER INFORMATION

This safety data sheet has been prepared in the ŁUKASIEWICZ Research Network – INDUSTRIAL CHEMISTRY RESEARCH INSTITUTE on the basis of the recipe and data delivered by the manufacturer.

Data for the registered substances: <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

The information contained in this safety data sheet describes the product exclusively from the safety requirements perspective. The user is responsible for setting up the conditions for safe use of the product and bears a sole responsibility for the consequences of its incorrect use.

Abbreviations:

WEL	Workplace Exposure Limits
vPvB	very Persistent very Bioaccumulative.
PBT	Persistent, Bioaccumulative, Toxic.
LD ₅₀	Lethal dose, median dose, where 50 % of test subject dies.
LC ₅₀	Lethal concentration, median concentration where 50 % of test subjects dies.
EC ₅₀	The effective concentration of substance that causes 50% of the maximum response.
BCF	Biological Concentration Factor.
ADR	Agreement on Dangerous Goods by Road
RID	Regulations Concerning the International Transport of Dangerous Goods by Rail
IMDG	International Maritime Dangerous Goods Code
IATA	International Air Transport Association

Update (2): change of types of pigments, changes introduced by regulation 2020/878, changes in Section 8, update of legal acts in section 15.1.

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