

SAFETY DATA SHEET

Prepared in the format conforming to the Commission Regulation (EU) 2015/830 of 28 May 2015 amending 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 L132 of 29 May 2015)

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

1.1 Product identifier

Maderm pigment - permanent make-up ink

(PMP-18 B187 MADERM pigment Blue, PMP-22 C084 MADERM pigment Toffee, PMP-20 C099 MADERM pigment Dolce, PMP-46 C110 MADERM pigment Americana, PMP-19 C123 MADERM pigment Muscat, PMP-34 C126 MADERM pigment Black, PMP-04 C127 MADERM pigment Arabica, PMP-26 C129 MADERM pigment Hollywood Kiss, PMP-17 C134 MADERM pigment Frappe, PMP-04 C136 MADERM pigment Arabica, PMP-09 C161 Mokka, PMP-57 C161 MADERM pigment Light One, PMP-57 C164 MADERM pigment Light One, PMP-54 C165 MADERM pigment Candy Pink, PMP-55 C166 MADERM pigment Rosaline, PMP-56 C167 MADERM pigment Green, PMP-39 C168 MADERM pigment Espresso, PMP-56 D001 MADERM pigment Charmine Rose, PMP-36 D085 MADERM pigment White, PMP-38 C019 MADERM pigment Red Wine, PMP-45 C093 MADERM pigment Paloma, PMP-61 B191 MADERM pigment Medical 4, PMP-33 C017 MADERM pigment Medical 3, PMP-01 C067 MADERM pigment Medical 2, PMP-06 B012 MADERM pigment Medical 1, PMP-14 C091 MADERM pigment Madera, PMP-59 D020 MADERM pigment Lip Light, PMP-51 D014 MADERM pigment Golden Brown, MMP-17 D034 MADERM pigment Frappe microblading Ink, PMP-03 D026 MADERM pigment Dark Blond, PMP-21 D033 MADERM pigment Cream Cherry, PMP-12 C048 MADERM pigment Brasiliana, MMP-04 D055 MADERM pigment Arabica microblading Ink, MMP-39 D-031 MADERM pigment Espresso microblading Ink; PMP-62 F027 MADERM pigment Barbados, PMP-48 F007 MADERM pigment Barbie Pink, PMP-32 E003 MADERM pigment Nude)

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

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.

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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:

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.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

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

(PMP-18 B187 MADERM pigment Blue, PMP-22 C084 MADERM pigment Toffee, PMP-20 C099 MADERM pigment Dolce, PMP-46 C110 MADERM pigment Americana, PMP-19 C123 MADERM pigment Muscat, PMP-34 C126 MADERM pigment Black, PMP-04 C127 MADERM pigment Arabica, PMP-26 C129 MADERM pigment Hollywood Kiss, PMP-17 C134 MADERM pigment Frappe, PMP-04 C136 MADERM pigment Arabica, PMP-09 C161 Mocca, PMP-57 C161 MADERM pigment Light One, PMP-57 C164 MADERM pigment Light One, PMP-54 C165 MADERM pigment Candy Pink, PMP-55 C166 MADERM pigment Rosaline, PMP-56 C167 MADERM pigment Green, PMP-39 C168 MADERM pigment Espresso, PMP-56 D001 MADERM pigment Charmine Rose, PMP-36 D085 MADERM pigment White, PMP-38 C019 MADERM pigment Red Wine, PMP-45 C093 MADERM pigment Paloma, PMP-61 B191 MADERM pigment Medical 4, PMP-33 C017 MADERM pigment Medical 3, PMP-01 C067 MADERM pigment Medical 2, PMP-06 B012 MADERM pigment Medical 1, PMP-14 C091 MADERM pigment Madera, PMP-59 D020 MADERM pigment Lip Light, PMP-51 D014 MADERM pigment Golden Brown, MMP-17 D034 MADERM pigment Frappe microblading Ink, PMP-03 D026 MADERM pigment Dark Blond, PMP-21 D033 MADERM pigment Cream Cherry, PMP-12 C048 MADERM pigment Brasiliana, MMP-04 D055 MADERM pigment Arabica microblading Ink, MMP-39 D-031 MADERM pigment Espresso microblading Ink; PMP-62 F027 MADERM pigment Barbados, PMP-48 F007 MADERM pigment Barbie Pink, PMP-32 E003 MADERM pigment Nude)

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

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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.

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.

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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.

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	ppm
			474	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.

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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

9.1 Information on basic physical and chemical properties

- a) Appearance
Liquid with colour dependent on specifications (added pigment).
- b) Odour
No data available.
- c) Odour threshold
No data available.
- d) pH
No data available.
- e) Melting/freezing point
No data available.
- f) Initial boiling point and boiling range
> 100 °C
- g) Flash point
Non-flammable product.
- h) Evaporation rate
No data available.
- i) Flammability (solid, gas)
Not applicable.
- j) Upper/lower flammability or explosive limits
Not applicable. The mixture does not pose an explosion hazard.
- k) Vapour pressure
No data available.
- l) Vapour density
No data available.
- m) Relative density
0.9 – 1.36 (water = 1)
- n) Solubility(ies)
No data available.
- o) Partition coefficient: n-octanol/water
No data available.
- p) Auto-ignition temperature
No data available.
- q) Decomposition temperature
No data available.
- r) Viscosity

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- No data available.
- s) Explosive properties
Does not pose an explosion hazard.
- t) Oxidising properties
No data available.
- 9.2 Other information
Not known.

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 toxicological effects

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 :

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:

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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.

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.

12.6 Other adverse effects

No data available.

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.

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SECTION 14: TRANSPORT INFORMATION

ADR/RID, IMDG, IATA

- 14.1 UN 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 Transport in bulk according to Annex II of MARPOL and the IBC Code
Not applicable.
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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);
COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
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 1-14).
 - 15.2 Chemical safety assessment
Supplier has not assessed the chemical safety of the mixture (mixture does not pose a risk).
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SECTION 16: OTHER INFORMATION

This safety data sheet has been prepared in the LUKASIEWICZ 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>

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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

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