

BIOTIC PHOCEA – DERMAL IMPLANT

Safety Data Sheet

SECTION 1 - IDENTIFICATION OF THE PRODUCT AND COMPANY INFORMATION

Product name:

Each product is identified by a product name, which is based on the colour shade of the pigment, and a product reference made up of 2 letters and 2 numbers.

Product use:

Medical Tattooing and Permanent Makeup.

Company information:

Manufacturer: Laboratoires BIOTIC PHOCEA 150, rue de Crimée 13003 - Marseille (France)

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Emergency numbers

- France: SAMU: 15 SOS Médecins: 0820 33 24 24
- France and Abroad:
 - Poisons Information Service in Paris: Tel.: +33(0)1 40 05 48 48
 - Poisons Information Service in Marseille: Tel.: +33(0)4 91 75 25 25
 - Poisons Information Service in Lyon : Tel. : +33(0)4 72 11 69 11

SECTION 2 – COMPOSITION INFORMATION ON INGREDIENTS

The pigments entering the composition of the pigment dispersion are referenced by **Colour Index** Number, preceded by the \pm symbol. These pigments are approved for use on skin and mucous membranes and prolonged contact with these, including eye contour, in compliance with Annex IV of the European Regulation No 1223/2009.

Other ingredients included in the formula are listed in the table below:

Chemical	CAS #	EINECS #	INCI	CMRs
1,2-propanediol	57-55-6	200-338-0	Propylene glycol	0
1,2,3-propanetriol	56-81-5	200-289-5	Glycerine	0
Sodium hydroxide	1310-73-2	215-185-5	Sodium hydroxide	0
2-hydroxypropanoic acid	79-33-4	201-196-2	Lactic acid	0
Isopropanol propan-2-ol	67-63-0	200-661-7	Isopropyl alcohol	

Hazard Symbols:

X Risk Phrases:

R Safety Phrases:

Explosive: E,

Oxidizing: O,

Extremely flammable: F+,

Highly flammable: F,

Flammable: R10,

Very toxic: T+,

Toxic: T,

Harmful: Xn,

Corrosive: C,

Irritant: Xi,

May cause sensitization: R42 and/or R43,

CMRs : Carcinogenic: Carc cat., Mutagenic: Muta cat., Reprotoxic: Repr. Cat.,

Dangerous for the environment: N and/or R52, R53, R59.

Ingredients which may pose a hazard when handled as part of the manufacturing process:

1. 2-hydroxypropanoic acid (lactic acid): R35 (May cause severe burns), **S26** (In the event of accidental eye contact, immediately flush eyes with plenty of water), **S36/37/39**, (Wear protective clothing and gloves. Wear eye and face protection), **S45** (In the case of accidental exposure or if you feel unwell, seek medical advice immediately)

Acute toxicity:	LD ₅₀ oral route (rat): 3,730 mg/kg
Eye contact:	May cause chemical burns and permanent eye damage.
Skin contact:	May cause skin irritation.
Ingestion:	May cause irritation to mouth, throat and digestive tract. Ingestion of large amounts may cause mild damage to kidneys. This risk is negligible owing to the small quantities used in the end product, except in the case of massive ingestion.
Inhalation:	May cause irritation to the respiratory tract.
Chronic exposure:	No carcinogenic effect was observed during animal tests. No mutagenic effect was observed on bacterial and mammalian cell cultures.

Sodium hydroxide (Caustic Soda): R35, S26, S36/37/39, S45

The solution is prepared with pure caustic soda flakes: 10g of flakes mixed with 90g of water for a solution containing 10% NaOH

May cause severe burns.

Eye contact:	May cause chemical burns and permanent eye damage. In the event of accidental eye contact, flush eyes with plenty of water holding eyelids open for 10 minutes. Seek medical advice immediately.
Skin contact:	May cause severe skin burns and induce skin necrosis. Rinse off with plenty of water and dab with polyethylene glycol 400. Remove clothing immediately if contaminated by splash or spill and seek medical advice.
Ingestion:	May cause irritation to mouth, throat and digestive tract. Do not induce vomiting. Give large quantities of water. Seek medical advice immediately.
Inhalation:	May result in severe burns to the respiratory tract. Remove victim to fresh air. Seek immediate medical attention.
Chronic exposure:	When handling, wear full protective clothing, including eye, face and head protection, and gloves.

Isopropyl alcohol (isopropanol): H 225 (Highly flammable liquid and vapours), **S26, S36/37/39, S45, H319** (May cause severe eye irritation), **P210** (Keep away from heat/sparks/open flame/hot surfaces), **P261** (Avoid breathing dust)

Acute toxicity:	LD ₅₀ oral route (rat): 5,045 mg/kg
Eye contact:	Irritation, tearing, burning. Flush with plenty of water.
Skin contact:	Dries out skin. Rinse off with plenty of water, wear gloves.
Inhalation:	May cause irritation to the respiratory tract. Remove victim to fresh air.

Powder pigments: R35, S26, S36/37/39, S45

Acute toxicity:	LD ₅₀ oral route (rat): > 2,000 mg/kg
Eye contact:	May cause eye irritation.
Skin contact:	May cause mild skin irritation.
Ingestion:	May cause stomach irritation, coughing, pain, vomiting blood. This risk is negligible owing to the small quantities used in the end product, except in the case of massive ingestion.
Inhalation:	May cause severe irritation to the respiratory tract. May cause asphyxiation in the case of massive inhalation. Face protection is compulsory when handling powder pigments. This risk is very low when handling the end product as it is supplied in a non-volatile liquid form, except in the case of massive inhalation.

Chronic exposure: Metal oxides contain traces of heavy metals and azo pigments which can release aromatic amines. Face protection and gloves are compulsory when handling powder pigments.

Black iron oxide: R35, S26, S36/37/39, S45

Hazards: see powder pigments above.

Ignition hazard: Black iron oxide should be stored at a temperature of 25°C, and may lose its colour if it is stored at a temperature above 80°C. When exposed to an open flame, black iron oxide may ignite and release toxic fumes (melting point > 1,000°C).

SECTION 3 – HAZARDS IDENTIFICATION

Product classification: NON TOXIC. Ingredients pose 'negligible' risk as they are used in very small quantities. **S36/37/39**, (*Wear protective clothing and gloves. Wear eye and face protection*)

Eye contact: Contains Isopropyl alcohol which may cause eye irritation.

Skin contact: Contains Isopropyl alcohol which may cause mild skin irritation.

Ingestion: May irritate mucous membranes. This risk is negligible owing to the small quantities used in the end product, except in the case of deliberate massive ingestion.

Inhalation: Isopropyl alcohol vapours may cause mild irritation. Do not breathe fumes. Do not take the multi-dose bottles to pieces.

Chronic exposure: Possible skin irritation and dryness. Always wear gloves.

SECTION 4 – FIRST AID MEASURES

Immediate medical attention is required in case of accidental exposure (ingestion, inhalation).

Other cases: Follow the instructions above and seek medical advice if symptoms persist.

Eye contact: Flush with plenty of water for 10 minutes, and seek medical advice.

Skin contact: Remove clothing and wipe off. Clean skin with mild soap and rinse off with plenty of water

Inhalation: In case of minimal exposure, symptoms may include coughing. Do not intervene and seek medical advice. In case of high exposure, symptoms may include asphyxiation. Call emergency number and give artificial respiration.

First aid for ingestion: If large amounts have been ingested, seek medical advice.

SECTION 5 – FIRE FIGHTING PROCEDURES

Flash Point (°C)	Flammable limit (vol%)	Auto ignition temperature (vol%)
Unknown	Unknown	Unknown

Method

Extinguishing Media: Small fires: use a dry powder or a carbon dioxide extinguisher.
Large fires: use a foam spray extinguisher or a fire hose.

Firefighting procedures: Eliminate all sources of ignition (flame, gas), cut off electrical power by switching off the circuit breaker. Shut doors and windows. Fire fighters should wear structural firefighter's protective clothing with self contained breathing apparatus. Unusual fire hazards: Unknown.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal precautions:	Remove all flammable materials, ventilate premises, wear protective clothing and gloves, and face protection.
Accidental release measures:	Mop up spilled material with absorbent pads, sawdust or sand. Pick up spilled material and dispose of in leak proof bags. Wash the floor with a grease removing detergent and rinse thoroughly.
Environmental precautions:	Do not flush product, detergent or contaminated water in the general waste water system.

SECTION 7 – HANDLING AND STORAGE

Handling:	Avoid contact with skin and eyes. Wear protective clothing and gloves. Wear eye and face protection. If some of the product accidentally spills over, clean up immediately. Do not flush product, detergent or contaminated water in the general waste water system. Ventilate premises.
Storage:	Store at 18-25°C in a well ventilated room, keep away from dust and light. Keep out of the reach of children.

SECTION 8 – EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational exposure control:	Personnel handling this product must have regular medical check-ups in order to detect symptoms of allergy and intolerance, or chronic irritation.
Personal Protective Equipment:	Protective equipment and safety measures on premises must comply with the European standard EN166. Premises should be properly ventilated and should be equipped with an emergency eyewash station, and a shower. Room temperature should range between 20-25°C. Personnel should wear full protective clothing in order to prevent any accidental contact with skin, eyes and hair: protective suit (Tyvek), mobcaps and forage caps, face protection, gloves (nitrile gloves are preferred over latex and PVC), boots and overshoes. For eye protection, wear large unvented goggles or a full face visor.
Environmental protection:	Waste and residues should not be flushed into the environment or the general wastewater collection system: dispose of in containers and leak proof bags in accordance with local authority requirements.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Viscous liquid
Colour	Variable
Odour	Light odour of alcohol
pH	6 - 7.2
Flammability and flash point	Non-flammable
Explosion risk	None
Relative density	900 – 1,400
Solubility in water	Soluble
Solubility in fat	Non soluble

Viscosity	40 - 80.000 Cps
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SECTION 10 – STABILITY AND REACTIVITY

Stability: stable

Hazardous decomposition products: unknown

Conditions to avoid: no particular precautions are required, with the exception of storage requirements

Incompatibility with other materials: not relevant.

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute oral toxicity	Unknown
Acute skin toxicity	Unknown
Acute toxicity by inhalation	Purely mechanical effect + mild alcohol vapours
Skin irritation	Non-irritant in normal conditions of use
Eye irritation	Low, depending on colour
Sensitization	Risk of sensitization to titanium (skin tone shades) and chromium (green and blue-green shades)
Mutagenicity	Unknown
Chronic toxicity	Unknown (no known toxicity after 7 years use in humans)

This product does not pose any specific toxic risk. Ingredients which may eventually pose a toxic risk are:

- 2-hydroxy-1,2,3-propanetricarboxylic acid,
- 2-hydroxypropanoic acid,
- isopropanol, propan-2-ol

This toxic risk remains low and may be considered negligible owing to the small quantities used in the end product.

SECTION 12 – ECOLOGICAL INFORMATION

The ingredients contained in the end product as well as the manufacturing process pose a low ecological risk. This risk may be removed by not rinsing empty bottles/packaging, and disposing of waste in compliance with applicable requirements (see Section 13)

- Ecotoxic data

Acute toxicity on fish	Acute toxicity on daphnids	Acute toxicity on algae	Other acute or chronic effects on fauna and flora	Bioconcentration	Inhibition of microorganism activity
Unknown	Unknown	Unknown	Unknown	Unknown	Unknown

- Chemical data

Persistence and degradability	Bioaccumulation potential	Other harmful effects
Unknown	Unknown	Unknown

Environmental toxicity has not yet been fully investigated, therefore no criteria has been determined in terms of ecotoxicity.

Do not dispose of product in general waste, avoid contamination of drinking water and food.

SECTION 13 – DISPOSAL CONSIDERATIONS

Although this product is not considered dangerous, it should be disposed of in specific containers and not in general waste. Please comply with local legislation. Packaging in which the products are sold are made of glass or recyclable plastic. Dispose of infectious waste in infectious waste containers. Dispose of non-infectious waste in your local recycling centre with solvents and paints.

SECTION 14 – TRANSPORT INFORMATION

UN Number	Class	Proper shipping name	ADR pack group	Marine pollutant	Other
Non-classified				No	Not relevant

SECTION 15 – REGULATORY INFORMATION

This product is not subject to French and International regulations for dangerous substances.

Hazard Symbol: Xi (2-hydroxy-1,2,3-propanetricarboxylic acid and 2-hydroxypropanoic acid)

Risk Phrases: R36: Irritating to eyes.

R38: Irritating to skin.

R41: Risk of serious damage to eyes.

Safety Phrases: S24: Avoid contact with skin.

S26: In case of contact with eyes, flush immediately with plenty of water and seek medical advice.

S37/39: Wear protection gloves. Wear eye and face protection.

SECTION 16 – OTHER INFORMATION

Ingredients contained in the end product which pose a mild toxic risk are:

- 2-hydroxy-1,2,3-propanetricarboxylic acid: R36
- 2-hydroxypropanoic acid: R38 and R41
- Isopropanol propan-2-ol

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If this product is mixed with a non-compliant substance, BIOTIC PHOCEA will not be held responsible for the consequences of this. BIOTIC PHOCEA assumes no responsibility for the improper use of this product: please comply with the directions for use printed on the packaging.

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