

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

Dermo Filler

1. Identification of the substance/mixture and company

Trade name:	Dermo Filler
INCI	L-ornithine, amino acid obtained by biotechnology from vegetable starch, encapsulated in an Ionosome™
CAS No. :	Water, Propanediol, Ornithine, Phospholipids, Glycolipids
EINECS No. :	7732-18-5, 504-63-2, 70-26-8, 8002-43-5, -
REACH registration No. :	231-791-2, 207-997-3, 200-731-7, 232-307-2, -
Utilization:	-
Supplier company identification:	Raw material for cosmetic use
Emergency:	Elemental SRL, Piața Cazărmii no.15, 410188-Oradea, jud.Bihor, Romania Tel/Fax: +40259-436.755, www.ellemental.com RO: număr național pentru cazuri de urgență: 021 3183606 Institutul de Sănătate Publică București. International emergency number: +49 180 2273-112

2. Hazards Identification

2.1. Adverse human health effects: According to our knowledge, no specific risks when handled in accordance with good occupational hygiene and safety practices.

2.2 Environmental effects: Presents no particular risks to the environment, provided the disposal requirements (see section 13) and national or local regulations are complied with.

2.3 Physical and chemical hazards:

Fire or explosion: According to our knowledge, no specific hazard under normal conditions of use.

2.4 Classification of the product: This product is not classified as a hazardous mixture according to CLP regulation (EC) n°1272/2008.

3. Declaration of ingredients

3.1. Substances

NA

3.2. Mixtures

Water (CAS: 7732-18-5; EINECS: 231-791-2); Propanediol (CAS: 504-63-2; EINECS: 207-997-3); Ornithine (CAS: 3184-13-2; EINECS: 221-678-6); Phospholipids (CAS: 8002-43-5; EINECS: 232-307-2); Glycolipids (CAS: 190524-47-1; EINECS: -); Glycerin (CAS: 56-81-5; EINECS: 200-289-5); Sodium levulinate (CAS: 19856-23-6; EINECS: 243-378-4); Sodium anisate (CAS: 536-45-8; EINECS: 208-634-1); Tocopherol (CAS: 59-02-9; EINECS: 200-412-2); Helianthus Annuus Seed Oil (CAS: 8001-21-6; EINECS: 232-273-9).

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For detailed Compositional breakdown see TDS document

3.3. Hazardous constituents: None

4. First aid measures

Skin contact: Wash with soap and plenty of water. Consult a doctor if necessary.

Eye contact: Rinse with plenty of water immediately and extended in keeping the eyes disregarded. Consult an ophthalmologist.

Ingestion: If the conscience is complete, let him/her drink water. Never give anything to drink to an unconscious person. Consult a doctor.

Inhalation: Move the affected person away from the contaminated area and into the fresh air. Consult a doctor if necessary.

5. Fire fighting measures

5.1. Flammability: The product is not flammable.

Suitable extinguishing media: Carbon dioxide (CO₂), powders, foam.

Not suitable extinguishing media: None to our knowledge. In case of fire nearby, use suitable extinguishing agents.

5.2. Specific hazards:

Under the action of heat or during combustion: May form toxic and irritating vapors (carbon oxides CO and CO₂).

Specific fire fighting methods: Avoid the dumping of extinguishing water in the environment. Do not attempt to fight the fire without suitable protective equipment.

Protection of fire-fighters: Complete protective clothing. Self-contained and insulating breathing apparatus.

6. Accidental release measures

Personal precautions: Use individual protective equipment.

Environmental precautions: Contain the spilled material by bundling. Do not allow product to spread into the soil and to enter sewers/ surface or ground water.

Methods for cleaning up: Absorb spillage with inert absorbent material (earth or sand). Wash non-recoverable remainder with large amounts of water. Dispose of at a licensed waste collection point.

Further information: Warning: this product can cause the floor to be slippery.

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7. Handling and storage

7.1. Handling

- Technical measures: Stir well before use and reclose packaging after use.
- Precautions: Avoid contact with skin and eyes. Keep away from food and drinks. Wash hands and any other area exposed with soap and water before eating, drinking, smoking and before leaving work.

7.2. Storage

Store the container tightly closed in a dry area, protected from air and direct light, and at temperatures lower than 25°C.

Recommended packaging materials: Original packaging.

8. Exposure controls / personal protection

Engineering measures: No specific measures are required provided the product is handled in accordance with the general rules of occupational hygiene and safety.

Exposure limit values: no data available

Personal protective equipment:

- Respiratory protection: Not necessary
- Hand protection: Protective rubber gloves. The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard EN 374. Breakthrough time: refer to the recommendations of the supplier.
- Eye protection: Safety glasses.
- Body and skin protection: Wear a protective chemical proof clothing.

9. Physical and chemical properties

Aspect : Liquid

Color : Off-white to pale yellow

Odor : Characteristic

pH (pure) : [4.0 ; 6.0]

Water solubility : Dispersible

Oil solubility : Insoluble

Ethanol solubility : Insoluble

Boiling point (°C): Not determined

Melting point (°C): Not applicable

Flash point (°F): > 250

Self-igniting temperature (°C): Not determined

Viscosity: Not determined

Partition coefficient (n-octanol/water): Not determined

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10. Stability and reactivity

10.1. Stability

Stable at temperatures lower than 25°C and under normal conditions of use.

10.2. Hazardous reactions

- Conditions to avoid: light exposure and heat
- Materials to avoid: Strong oxidizing agents, strong acids, strong bases

10.3. Hazardous decomposition products

During combustion or thermal decomposition (pyrolysis), it may release: toxic and irritating vapors (CO, CO₂).

11. Toxicological information

11.1. Acute toxicity

No specific data available. According to our knowledge, no specific risk when handled in accordance with good occupational hygiene and safety practices.

- Propane-1,3-diol:

LD50 (oral, rat): 15000 mg/kg: not toxic (source: supplier's data)

-Ornithine:

Data available on a similar product, L-Ornithine HCl:

LD50 (oral, rat) of L-Ornithine HCl : 10000 mg/Kg: not toxic

Source: TOXNET basis (Journal of Pharmaceutical Sciences. Vol. 62, Pg. 49, 1973)

- Phospholipids:

LD50 (oral, rat): > 16000 mg/kg: not toxic (source: CIR report (IJT 20(S1):21-45,2001)

11.2. Primary irritation:

Data Method Concentration Result Source

Skin irritation: Patch-Test /48h product diluted at 4% Non irritant Study Evic France-I11-1099/11.3265

Eye irritation: HET-CAM product diluted at 4% Weakly irritant Study n°B11 2065 / 11-3265

Chronic effects:

Data Method Concentration Result Source

Sensitization HRIPT (101 volunteers) product diluted at 4% No evidence of Study n°PII30175 sensitization

Mutagenicity AMES test (OECD 471) pure product Non-mutagenic Study n°B-01446

Data available on ingredients:

-Propane-1,3-diol:

Sensitization: no sensitizing effects on laboratory animals.

Mutagenicity: tests made on bacteria cultures or mammalian cells does not point out mutagenic effects.

Chronic toxicity: NOAEL (oral, rat): 1000 mg/kg

Source: supplier's data

- Phospholipids:

Sensitization: Clinical studies (Patch tests) made on cosmetic formulations containing lecithin (between 0.5-5%) show that this raw material is not sensitizing and generally non-irritating.

Mutagenicity (AMES test): Not mutagenic

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Chronic toxicity, cancerogenicity, reproduction toxicity: data available in the CIR report
Reference: CIR report (IJT 20(S1):21-45,2001)

11.3. Other data:

- Phototoxicity test (3T3 NRU - OECD 432) - tested at 4%: Non-phototoxic

Source: Study n°B12 0577 / 12-0592

- Phospholipids contained in the product were CIR reviewed.

Conclusions of this report mention that lecithin is safe as used in rinse-off products but recommend a concentration lower than 15% in leave-on products. Furthermore, lecithin should not be used in cosmetic products in which N-nitroso compounds may be formed (source: IJT 20(S1):21-45, 2001).

12. Ecological information

12.1. Toxicity

Biodegradability: Easily biodegradable (method: OECD 301 D)
Source: Study made in December 2014

Bioaccumulation: Partition coefficient n-octanol/water: Not determined

Ecotoxicity: Effects on the aquatic environment :Aquatic toxicity EC50 (Daphnia: Daphnia magna)/ 48 h = 3.09 g/L
Method: OECD 202
Source: Study made in December 2014

13. Disposal considerations

13.1. Appropriate disposal / Product:

Recommendation: Do not empty into drains or the aquatic environment. This material and its packaging must be disposed of in a safe way. Waste disposal according to EC directives 75/442/EEC and 91/689/EEC on waste and hazardous waste in their latest versions.

13.2. Contaminated packaging:

Recommendation: empty and non-polluted packaging may be recycled. Jerricans not properly emptied are special wastes.

Note: The user's attention is drawn to the possible existence of specific European, national or local regulations regarding disposal.

14. Transport information

14.1. LAND TRANSPORT ADR/RID

Not regulated

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14.2. MARITIME TRANSPORT IMDG

Not regulated

14.3. AIR TRANSPORT IATA

Not regulated

15. Regulatory information

15.1. EU regulation

Chemical Safety Assessment: chemical safety assessments of substances contained in this mixture have not been carried out yet, except for Propanediol. Propane-1,3-diol was registered in 2010 by the supplier according to REACH regulation (EC) n°1907/2006. However, detailed exposure scenarios haven't been received yet.

Label elements according to CLP regulation n°1272/2008:

- Hazard pictograms: None
- Signal words: None
- Hazard statements: None
- Precautionary statements: None

International regulations:

- CTFA: all the ingredients of this mixture are listed
- European inventory CosIng: all the ingredients of this mixture are listed
- Regulation in USA: based on the conclusions of the CIR report on lecithins and hydrogenated lecithins.
- Note: the regulatory information given above only mention the main regulations specifically applicable to the product described in this MSDS. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. We recommend you to refer to all international, national or local regulations or provisions.

16. Additional information

16.1 Abbreviations:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

CAS: Chemical Abstracts Service (division of the American Chemical Society).

CLP: Classification, Labeling, Packaging.

DNEL: Derived No Effect Level.

EINECS: European Inventory of Existing Commercial Chemical Substances.

GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

IATA: International Air Transport Association.

IATA-DGR: Dangerous Goods Regulation by the "International Air Transport Association" (IATA).

ICAO: International Civil Aviation Organization.

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO).

IMDG: International Maritime Code for Dangerous Goods.

INCI: International Nomenclature of Cosmetic Ingredients.

LTE: Long-term exposure.

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PNEC: Predicted No Effect Concentration.

RID: Regulation Concerning the International Transport of Dangerous Goods by Rail.

STE: Short-term exposure.

STEL: Short Term Exposure limit.

STOT: Specific Target Organ Toxicity.

Disclaimer:

This material safety data sheet does not constitute a guarantee of the properties of the product and is not a contractual legal report. The information is given in good faith on the basis of our best knowledge of the product at the indicated time. However, we cannot accept responsibility or liability for any consequences arising from its use, no warranty for correctness and completeness is given. We caution the users against the incurred possible risks when the product is used at other ends than the use for which it was initially planned. It is the user's responsibility during handling, storage and product use to consult the main regulatory texts in force regarding workers and environment protection.