

## MATERIAL SAFETY DATA SHEET

Product: **Estesil H<sub>2</sub>TOP** Mono Implant

Issue Date: August 23, 2017

Version: 1

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier:

**Estesil H<sub>2</sub>TOP** Mono Implant

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

**Identified uses:** Medicale / paramedicale.

1.3 Details of the supplier of the safety data sheet:

**Tokuyama Dental Italy srl**

Indirizzo: Via dell'artigianato, 7, 36030 Montecchio Precalcino (VI) ITALY

Tel.: +39 0445 334 545

Fax: +39 0445 334 776

E-mail: [info@tokuyama.it](mailto:info@tokuyama.it)

1.4 Emergency telephone number:

Regional Medicines and Poisons Information Centre NI

Niguarda Hospital Ca' Granda

Piazza Ospedale Maggiore 3

Milan 20162

TEL: +39 02 6610 1029

FAX: +39 02 6444 2768

<http://www.ospedaleniguarda.it/struttura/Centro-antiveleni>

<http://www.who.int/ipcs/poisons/centre/en/>

### SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

The product has been classified according to the current regulations.

**Classification (EC 1272/2008):**

Health hazards:

Specific Target Organ Toxicity - Repeated Exposure Category1

Causes organ damage in case of prolonged or repeated exposure.

**Riepilogo dei pericoli:**

Physical hazards:

No specific recommendation.

Health hazards:

Inhalation:

Quartz / cristobalite: Encapsulated in the polymer, this product does not appear to pose any health hazards when treated under normal conditions of use. Although classified according to CE criteria, this product is exempted from labeling in accordance with Article 23 and Annex 1 (section 1.3.4.1) of Directive 1272/2008.

Contact with eyes:

No specific symptoms are reported

Skin contact:

No specific symptoms are reported

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Ingestion:	No specific symptoms are reported
Other health effects:	No other information provided.
Environmental hazards:	Not considered dangerous for the environment.
2.2 Elements of the Label:	Safety data sheet available on request.
2.3 Other hazards:	Chemical compounds containing silicon-hydrogen bonds (SiH). This product can generate hydrogen gas. For more information see § 10: "Stability and Reactivity".

**SECTION 3: Composition/information on ingredients**

3.2 Mixtures:

General information: Mixture of polyorganosiloxane, charge, additives.

Chemical name	Concentration	CAS NUMBER	CE N.	Registration Number REACH	Note
Quartz (SiO <sub>2</sub> )	<50%	14808-60-7			#

\*In the case of gaseous components the concentrations are expressed as a percentage of volume, in other cases as a percentage of weight.

#: # This substance has specified exposure limits for workplace.

PBT: persistent, bioaccumulative and toxic substance.

vPvB: very persistent and very bioaccumulable

Classification:

Chemical name	Concentration			Note
Quartz (SiO <sub>2</sub> )	DSD:	Xn; R48/20		
	CLP:	STOT RE 1;H372		

DSD: Directive 67/548 / EEC

CLP: Regulation No. 1272/2008

Full texts for all R Phrases and H Phrases are shown in step 16.

**SECTION 4: First aid measures**

**General information:** Get medical attention if symptoms occur. Store contaminated clothing in closed containers until disposal or decontamination.

**4.1 Description of first aid measures:**

<b>Inhalation:</b>	Not relevant.
<b>Eye contact:</b>	In case of contact with eyes, rinse thoroughly with clean water. Continue to rinse for at least 15 minutes.
<b>Skin contact:</b>	Remove contaminated clothing and shoes. Wash with soap and water.
<b>Ingestion:</b>	Do not induce vomiting. Rinse the mouth thoroughly with water.

**4.2 Most important symptoms and effects, both acute and delayed:** Not known.

**4.3 Indication of any immediate medical attention and special treatment needed:** Get medical attention if symptoms occur

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**Risks** No specific recommendation.

**Treatment:** No specific recommendation.

**SECTION 5: Firefighting measures**

**General Fire Hazards:** No specific recommendation.

**5.1 Extinguishing media:**

**Suitable extinguishing media:** Foam. Powder. Carbon dioxide (CO<sub>2</sub>).

**Unsuitable extinguishing media:** Do not use a jet of water as a means of extinction because it would extend the fire. Alkaline powders.

**5.2 Special hazards arising from the substance or mixture:**

This product can generate hydrogen gas. Vapors can form explosive mixtures with the air. For more information see § 10: "Stability and Reactivity".

**5.3 Advice for firefighters:  
Protective actions during firefighting**

Cool containers exposed to heat with water spray and remove them from the fire area if it can be done without risk.

**Special protective equipment for firefighters:**

Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing. Firefighter's clothing conforming to European standard EN469 (including helmets, protective boots and gloves) will provide a basic level of protection for chemical incidents.

**SECTION 6: Accidental release measures**

**6.1 Personal precautions:**

Wear suitable personal protective equipment. For individual protection equipment, see Section 8 of the SDS. Keep away from Alkal and caustic products. Eliminate all sources of ignition.

**6.2 Environmental Precautions:**

Collect leakage material. Avoid penetration in watercourses, drainage networks, basements or confined areas. Ventilate the swirling zone by means of mechanical means, avoiding the formation of explosive mixtures with the air.

**6.3 Methods and material for containment and cleaning up:**

Collecting container for spilled material must be labeled with the correct designation of the contents and the hazard symbol. Suitable containers: equipped with a degasser. Absorb with sand or other inert absorbent. DO NOT use basic substances. To clean the floor and objects contaminated by this product, use a suitable solvent (see § 9). Wash the area with plenty of water.

**Notification procedures:**

Caution: Contaminated surfaces may be slippery. For disposal information, refer to Section 13 of the SDS.

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**SECTION 7: Handling and storage**

- 7.1 **Precautions for safe handling:** Use mechanical ventilation in case of handling that causes vapor formation. Do not mix with incompatible materials. For more information see § 10: "Stability and Reactivity". Read and follow the manufacturer's recommendations.
- 7.2 **Conditions for safe storage, including any incompatibilities:** Store in a cool, dry, well-ventilated place. Keep away from incompatible materials, free flames and high temperatures. Store in the original sealed packaging. equipped with a degasator. Suitable containers: polyethylene. Steel drum coated with epoxy resin.
- 7.3 **Specific end use(s)** No data available.

**SECTION 8: Exposure Controls/personal protection**

- 8.1 **Control parameters:**  
**Occupational exposure limits:**  
**Quarzo/cristobalite:** Encapsulated in the polymer, this product does not appear to pose any health hazards when treated under normal conditions of use.
- 8.2 **Exposure controls:**  
Appropriate engineering controls: Avoid inhaling vapors and aerosols.
- Individual protection measures, such as personal protective equipment:**
- General informations:** Ensure adequate ventilation during the operation of vapor formation operations.
- Eye/face protection:** Wear protective goggles.
- Skin protection:**
- Hand protection:** Use protective gloves made of: Nitrile. Polyvinyl Chloride (PVC). Rubber or plastic.
- Other skin and body protection:** Wear appropriate clothing to prevent repeated or prolonged skin contact. Use suitable protective clothing.
- Respiratory protection:** No particular precaution.
- Hygiene measures:** Install an eyewash spot and a safety shower.
- Environmental controls:** No data available.

**SECTION 9: Physical and Chemical Properties**

- 9.1 **Information on basic physical and chemical properties:**
- Appearance:**
- Form:** Liquid
- Form:** Viscous

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<b>Colour:</b>	Purple
<b>Odour:</b>	Odorless
<b>Odour threshold:</b>	Not available.
<b>pH:</b>	Not available
<b>Freezing point:</b>	Not available.
<b>Boiling point:</b>	Not available.
<b>Flash point:</b>	200 °C (Vase closed second the norm ASTM D63.)
<b>Evaporation rate:</b>	Not available.
<b>Flammability (solid, gas):</b>	Not available.
<b>Upper flammability or explosive limits%:</b>	74 %(V) Hydrogen.
<b>Lower flammability or explosive limits %:</b>	4 %(V) Hydrogen.
<b>Vapour pressure:</b>	< 0,1 hPa (20 °C)
<b>Vapour density (ari=1):</b>	Not available.
<b>Relative density:</b>	1,4 (23 °C)
<b>Solubility(ies):</b>	
<b>Solubility in water:</b>	Practically insoluble Solubility (other):
<b>Etere dietilico.:</b>	Miscible (in all proportions)
<b>Solventi clorurati.:</b>	Miscible (in all proportions)
<b>Idrocarburi aromatici:</b>	Miscible (in all proportions)
<b>Idrocarburi alifatici:</b>	Miscible (in all proportions)
<b>Acetone.:</b>	Very little soluble.
<b>Etanolo.:</b>	Very little soluble.
<b>Partition coefficient (n-octanol/water):</b>	Not available.
<b>Auto-ignition temperature:</b>	500 °C Hydrogen.
<b>Decomposition Temperature:</b>	Not available.
<b>Viscosity:</b>	2 000 000 mm <sup>2</sup> /s (23 °C)
<b>Explosive properties:</b>	Not available.
<b>Oxidising properties:</b>	Not available.

**SECTION 10: Stability and reactivity**

10.1 <b>Reactivity:</b>	No other information provided.
10.2 <b>Chemical stability:</b>	The material is stable under normal conditions.
10.3 <b>Possibility of hazardous reactions:</b>	This product can generate hydrogen gas.
10.4 <b>Conditions to avoid:</b>	No other information provided.
10.5 <b>Incompatible materials:</b>	It develops a highly flammable gas (hydrogen) that causes fire or explosion hazards, in contact with: Strong oxidizing agents. Alkalies and caustic products. Mobile hydrogen chemical compounds, in the presence of metal salts and metal complexes.
10.6 <b>Hazardous decomposition products:</b>	Thermal decomposition or combustion can release carbon oxides and other toxic gases and vapors. Silica amorphous. Potentially Developable Hydrogen Quantities (l / kg of product): <5

**SECTION 11: Toxicological information**

**Information on toxicological effects**

<b>Inhalation:</b>	<b>Not available.</b>
<b>Ingestion:</b>	<b>Not available.</b>
<b>Acute toxicity - dermal:</b>	<b>Not available.</b>
<b>Acute toxicity - eye:</b>	<b>Not available.</b>

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**11.1 Information on toxicological effects:****Acute toxicity:****Ingestion:****Product:** Not classified for acute toxicity based on available data.**Contact skin:****Product:** Not classified for acute toxicity based on available data.**Inhalation:****Product:** No expected effect (estimation based on the substances present).**Repeated dose toxicity:****Product:** No expected effect (estimation based on the substances present).**Skin corrosion/irritation:****Product:** No expected effect (estimation based on the substances present).**Serious eye damage/irritation:****Product:** No expected effect (estimation based on the substances present).**Respiratory and skin sensitisation:****Product:** No expected effect (estimation based on the substances present).**Germ cell mutagenicity:****In vitro:****Product:** No expected effect (estimation based on the substances present).**In vivo:****Product:** No expected effect (estimation based on the substances present).**Carcinogenicity:****Product:** No expected effect (estimation based on the substances present).**Product:** Nessun dato disponibile.**Reproductive toxicity:****Product:** No expected effect (estimation based on the substances present).**Reproductive toxicity (fertility):****Product:** No data available.**Developmental Toxicity (Teratogenicity):****Product:** No data available.**Specific target organ toxicity - Single exposure:****Product:** No expected effect (estimation based on the substances present).**Specific target organ toxicity - Single exposure:****Product:** No expected effect (estimation based on the substances present).**Aspiration hazard:****Product:** No expected effect (estimation based on the substances present).**Other Adverse Effects:**

Unknown.

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**SECTION 12: Ecological Information****12.1 Toxicity:****Acute toxicity - fish:****Product:** No expected effect (estimation based on the substances present).**toxicity - aquatic****invertebrates:****Product:** No expected effect (estimation based on the substances present).**Tossicità cronica:****Pesce:****Product:** No expected effect (estimation based on the substances present).**Invertebrati Acquatici:****Product:** No expected effect (estimation based on the substances present).**Tossicità per le piante acquatiche:****Product:** No expected effect (estimation based on the substances present).**12.2 Persistence and degradability:****Biodegradazione:****Product:** Not available**Rapporto BOD/COD:****Product:** No data available.**12.3 Bioaccumulative potential:****Product:** No data available.**12.4 Mobility in soil:**

No data available.

**12.5 Results of PBT and vPvB assessment:**

No data available.

**12.6 Other Adverse Effects:**

Unknown.

**SECTION 13: Disposal considerations****13.1 Waste treatment methods:****General information:**

The user's attention is drawn to the possible existence of local waste disposal regulation.

**Disposal methods:**

Dispose of surplus products and those that cannot be recycled via a licensed waste disposal contractor. Waste, residues, empty containers, discarded work clothes and contaminated cleaning materials should be collected in designated containers, labelled with their contents. Incineration or landfill should only be considered when recycling is not feasible.

Contaminated packaging should be emptied as much as possible and equipped with a degassing device. Dispose of waste in an appropriate treatment and disposal center in accordance with applicable laws and regulations and product characteristics at the time of disposal. After cleaning, recycle or remove it at an authorized center.

**SECTION 14: Transport information****General:**

This material is not subject to shipping regulations.  
It is forbidden to pack with a breathable air vent cap.

**14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code.**

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**SECTION 15: Regulatory information**

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

National regulations.

**15.2 Chemical safety assessment:**

No data available.

**SECTION 16: Other information**

**Revision comments:**

Not relevant.

**Abbreviations of the legend or  
acronyms used:**

No data available.

**Main bibliographic references  
and data sources:**

No data available.

**R-phrases and hazard statements in the sections 2 e 3:**

H372 It causes damage to organs in case of prolonged or repeated exposure.

**Training advice:**

No data available.

**State of the inventory**

<b>AICS:</b>	Inventory or in accordance with inventory.
<b>DSL:</b>	Not in accordance with inventory.
<b>EU INV:</b>	Inventory or in accordance with inventory.
<b>ENCS (JP):</b>	Inventory or in accordance with inventory.
<b>IECSC:</b>	Inventory or in accordance with inventory.
<b>KECI (KR):</b>	Not in accordance with inventory.
<b>NDSL:</b>	Not in accordance with inventory.
<b>PICCS (PH):</b>	Not in accordance with inventory.
<b>Lista TSCA:</b>	Inventory or in accordance with inventory
<b>NZIOC:</b>	Not in accordance with inventory.
<b>TCSI:</b>	Not in accordance with inventory.

**Issue Date:**

July 21, 2017

**SDS N.:**

**Limitation of Liability:**

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