

SECTION 1 — Identification of the substance/mixture and the company/undertaking**1.1. Product identifier**

Mixture Identification:

Denomination:

VESTIGE IMPLA- CATALYST

Code:

1S6001

1.2. Relevant identified uses of the substance or mixture and discouraged uses

For professional use only. Silicone-A for dental impressions.

1.3. Safety Data Sheet Provider Information

Name

TRAYART srl

Via Paiette, 13/Q

35040 Castelbaldo (PD)

Italy

Tel. +39 0425 546515

Competent person responsible for the safety data sheet: info@trayart.it

1.4. Emergency telephone number

Phone: +39 0425-546515

SECTION 2 — Hazard identification**2.1. Classification of the substance or mixture**

Criteria EC Regulation 1272/2008 (CLP):

The product is not considered hazardous in accordance with EC Regulation 1272/2008 (CLP).

Adverse physicochemical effects on human health and the environment:

No other hazards

2.2. Labelling elements

Regulation EC 1272/2008, on the classification, labelling and packaging of substances and mixtures (CLP), does not apply to medical devices in the finished state used in direct physical contact with the human body as dictated by Art. 1.5, paragraph d). The product is therefore exempt from the CLP labelling obligation.

The product is not considered hazardous in accordance with EC Regulation 1272/2008 (CLP).

Hazard pictograms:

No Hazard

Statements:

No

Precautionary Tips:

No Special

Provisions:

EUH210 Safety Data Sheet available upon request.

Specific provisions in accordance with Annex XVII of REACH and its successive amendments:

No

2.3. Other hazards

Exposure to respirable crystalline free silica is not expected during normal use of this product. For more information, see section 11.

No PBT, vPvB or endocrine disruptors present in concentration $\geq 0.1\%$ Other hazards:
No other hazards

SECTION 3 — Composition/information on components

3.1. Substances

Non Applicable

3.2. Festschrift

Hazardous components under the CLP Regulation and related classification:

Qty	Name	Identity number.	Classification by category
$\geq 10\%$ - $< 12.5\%$	Cristobalite	CASE: 14464-46-1 EC: 238-455-4	STOT RE 1 H372 Proven risk serious effects on the organs (lungs) as a result of exposures or exposure prolonged inhalation.
$< 0.09\%$	octamethylcyclotetrasiloxane; [D4]	Number 014-018-00-1 Index: CASE: 556-67-2 EC: 209-136-7	Flam. Liq. 3 H226 Flammable liquid and vapours. Repr. 2 H361f Likely to impair fertility. Aquatic Chronic 1 H410 Highly toxic to aquatic organisms, causing long-term adverse

Nanofom substance:

None

HEADING 4 — First aid

4.1. Description of first aid measures

In case of contact with skin:

Wash thoroughly with soap and water.

In case of contact with the eyes:

In case of contact with eyes, wash immediately and thoroughly with water and consult a specialist.

If swallowed:

Do not induce vomiting under any circumstances. SEEK IMMEDIATE MEDICAL ATTENTION.

If inhaled:

Carry the victim outside and keep them warm and resting.

4.2. Main symptoms and effects, acute and delayed

None

4.3. Indication of any immediate medical care and special treatments needed

Treatment: None

HEADING 5 — Fire-fighting measures

5.1. Moyens d'extinction

Suitable extinguishing means:

Water.

Carbon dioxide (CO₂).

Extinguishing means that should not be used for safety reasons: None in particular.

5.2. Special hazards resulting from the substance or mixture Do not inhale the gases produced by explosion and combustion.

Combustion produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus.

Collect separately the contaminated water used to extinguish the fire. Do not pour it into the wastewater network.

If feasible from a safety point of view, move undamaged containers from the immediate danger zone.

HEADING 6 — Measures to be taken in the event of accidental dispersal

6.1. Personal Precautions , Protective Equipment and Emergency Procedures

For non-rescuers:

Wear personal protective devices. Take people to safety.

Refer to the protective measures outlined in points 7 and 8. For first aiders:

Wear personal protective devices.

6.2. Precautions for the protection of the environment

Prevent penetration into the ground/subsoil. Preventing runoff into surface water or in the wastewater system.

Retain contaminated wash water and dispose of it.

In the event of a gas leak or penetration into watercourses, soil or drainage systems, inform the responsible authorities.

Material suitable for collection: absorbent, organic, sand.

6.3. Containment and Cleaning Methods and Equipment

Wash with plenty of water.

6.4. Reference to other topics

See also paras. 8 and 13.

HEADING 7 — Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists. See also paragraph 8 for recommended protective devices. General advice on occupational hygiene:

Do not eat or drink during labor.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, beverages and animal feed. Incompatible materials:

See section 10.5. Indication for rooms: Properly ventilated rooms.

7.3. Specific end-use(s)

See section 1.2.

HEADING 8 — Exposure controls/personal protection

8.1. Control Parameters

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Cristobalite - CAS: 14464-46-1

Type OEL	TWA		Duration	SET		Duration	Note	Country
EU	0.1 mg/m ³		8 a.m.				Breathable	
TLV	0.1 mg/m ³		8 a.m.				Breathable	ITALY
ACGIH	0.025 mg/m ³		8 a.m.				(R), A2 - Pulm fibrosis, lung cancer	

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Type OEL	TWA		Duration	SET		Duration	Note	Country
No data available								

DNEL Exposure Limit Values Not Available

NECP exposure limit values Not available

8.2. Exposure controls

Precautions to take:

Properly ventilate the premises where the product is stored and/or handled.

Eye protection:

It is recommended to wear airtight protective glasses (EN 166).

Skin protection:

Use workwear and safety shoes for professional use (EN 14605).

Hand protection:

Protect your hands with work gloves (EN 374).

When choosing the material of work gloves, it is necessary to take into account the following factors (EN 374): compatibility, degradation, breakage time and equivalent permeability.

In the case of preparations, the strength of the work gloves must be tested before use insofar as it cannot be established a priori. The wear time of the gloves depends on the duration of the exposure.

Respiratory protection:

Where ventilation is insufficient, where exposure is prolonged, use a protective device of the respiratory tract.

The use of respiratory protection is necessary in the event that the technical measures adopted are not sufficient to limit the exposure of personnel to the threshold values taken into account (e.g. TLV-TWA).

Thermal hazards:

None

Environmental Exposure Controls: None

Appropriate technical controls None

HEADING 9 — Physical and chemical properties

9.1. Information on essential physical and chemical properties

Properties	value	Method:	Remarks
Physical Condition:	Viscous fluid	--	--
Colour:	white	--	--
Smell:	Odourless	--	--
Melting Point/Freezing Point:	Not available	--	--
Boiling point or initial boiling point and boiling range:	Not available	--	--
Inflammability:	Not available	--	--
Lower Limits and Upper Explosion:	Not available	--	--
Flash point:	Not available	--	--
Temperature Self-flammability:	Not available	--	--
Decomposition Temperature:	Not available	--	--
ph:	Not available	--	--
Kinematic viscosity:	Not available	--	--
Water solubility:	Insoluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or Relative Density:	Not available	--	--
Relative Vapor Density:	Not available	--	--
Particle characteristics:			
Particle Size:	Not available	--	--

9.2. Other information

No other important information

HEADING 10 — Stability and responsiveness

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

Stable under normal conditions

10.3. Potential for Hazardous Reactions

None

10.4. Conditions to avoid

Stable under normal conditions.

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

None.

HEADING 11 — Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

'For reasons of classification of health hazards (Part 3), exposure, information on mechanisms and metabolism studies are useful in determining the significance of an effect on humans. If this information raises doubts about its importance to humans, although the validity and quality of the data are indisputable, a lower classification may be justified. Where there is scientific evidence that the mechanism or mode of action is not important for humans, the substance or mixture shall not be classified' (Annex I, point 1.1.1.5, Regulation (EC) 1272/2008).

The monitoring of possible inhalation exposure carried out in the company according to industrial hygiene standards for pulp products and fluids revealed exposure levels to free crystalline silica (respirable fraction) below the limit of quantification of the method. Therefore, exposure is not expected during the use indicated in section 1.2 for this specific product.

However, the effective levels of free crystalline silica (respirable fraction) present at the workplace must be obtained by means of monitoring as required by the standards for the safety and health of workers.

Product toxicological information:

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- a) acute toxicity
Uncategorized

- b) Skin Corrosion/Skin Irritation
Uncategorized

- c) Serious eye damage/eye irritation
Unclassified

- d) respiratory or skin sensitization
Unclassified

- e) germ cell mutagenicity Uncategorized

- f) carcinogenicity
Uncategorized

- g) Reproductive toxicity Not
classified

- h) Specific target organ toxicity — single exposure Not classified

- i) Specific target organ toxicity – repeated exposure Unclassified

- j) Aspiration hazard
Not classified

Toxicological information on the main substances found in the product:

Cristobalite - CAS: 14464-46-1

(i) Specific target organ toxicity – repeated exposure:

Voie: Inhalation - Remarques: Silicosis, pulmonary fibrosis; Target organ: lungs - Source: (MSDS supplier).

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

(a) Acute toxicity:

Test: LC50 - Espèces: Rat 36 mg/l - Source: (OECD 403, GLP, rat, 4 h, ECHA dossier).

Test: LD50 - Voie: Peau - Espèces: Rat > 2000 mg/kg - Source: (similar to OECD 402, rat, ECHA dossier).

Test: LD50 - Voie: Orale - Espèces: Rat 4800 mg/kg - Source: (similar to OECD 401, rat, ECHA dossier).

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptors present in concentration \geq 0.1%

HEADING 12 — Ecological information

The product is not classified for chronic aquatic hazards.

Tests based on the bioavailability/release of D4 from a representative sample of polymeric silicones were performed using the OECD 29 method. The amount of D4 released from the tested polymers was found to be below the method's limit of quantification (i.e., 4.4 ppb) and therefore below the NOEC limit of 0.0044 mg/L for fish and 0.0079 mg/L for aquatic invertebrates, values that would lead to a classification as chronic aquatic toxicity.

12.1. Toxicity

Use the product rationally by avoiding dispersing it in nature.

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The product is classified: -

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) Acute aquatic toxicity:

Point final: IC50 - Espèces: Algues > 0.0022 mg/l - Durée h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Point final: LC50 - Espèces: Poissons > 0.0022 mg/l (Oncorhynchus mykiss, GLP, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.0044 mg/l (publication, Oncorhynchus mykiss, GLP, ECHA dossier).

Long-term toxicity to aquatic invertebrates:

Endpoint: NOEC - Species: Daphnia = 7.9 µg/L - Duration h: 21d EPA OTS 797.1330, Daphnia magna, ECHA dossier

12.2. Persistence and degradability

Cristobalite - CAS: 14464-46-1

Biodegradability: Not rapidly degradable

12.3. Potential for bioaccumulation

Cristobalite - CAS: 14464-

46-1 Not

bioaccumulative

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Test: Kow - Partition Coefficient 6.49 - Remarks: (Log Pow, ECHA dossier).

12.4. Mobility in the ground

Not available

12.5. PBT and vPvB assessment results

vPvB substances: None - PBT substances: None

12.6. Endocrine disrupting properties

No endocrine disruptors present in concentration \geq 0.1%

12.7. Other adverse effects

None

HEADING 13 — Disposal considerations**13.1. Waste treatment methods**

Recover if possible. Operate in compliance with local and national regulations.

HEADING 14 — Transport information**14.1. UN number or identification number**

Non-hazardous product within the meaning of transport regulations.

14.2. Official UN Transport Designation

Not available

14.3. Transport hazard class(es)

Not available

14.4. Packing Group

Not available

14.5. Environmental hazards ADR-

Environmental Pollutant: Non-

IMDG-Marine Pollutant: No

14.6. Special precautions to be taken by the user

Not available

14.7. Bulk shipping in accordance with IMO instruments

Non Applicable

SECTION 15 — Regulatory information**15.1. Substance- or mixture-specific regulations/legislation with respect to safety, health and environment**

Dir. 98/24/EC (Hazards arising from chemical agents at work)

Dir. 2000/39/EC (Occupational Exposure Limits)

Regulation (EC) No 1907/2006 (REACH)

Regulation (EC) No 1272/2008 (CLP)

Regulation (EC) No. 790/2009 (ATP 1 CLP) and (EU) No. 758/2013

Regulation (EU) No 2020/878

Regulation (EU) No 286/2011 (ATP 2 CLP)

Regulation (EU) No 618/2012 (ATP 3 CLP)

Regulation (EU) No 487/2013 (ATP 4 CLP)

Regulation (EU) No 944/2013 (ATP 5 CLP)

Regulation (EU) No 605/2014 (ATP 6 CLP)

Regulation (EU) No 2015/1221 (ATP 7 CLP)

Regulation (EU) No 2016/918 (ATP 8 CLP)

Regulation (EU) No 2016/1179 (ATP 9 CLP)

Regulation (EU) No 2017/776 (ATP 10 CLP)

Regulation (EU) No 2018/669 (ATP 11 CLP)

Regulation (EU) No 2018/1480 (ATP 11 CLP) 13
CLP)

Regulation (EU) No. 2019/521 (ATP 12 CLP)

Regulation (EU) No. 2020/217 (ATP 14 CLP)

Regulation (EU) No. 2020/1182 (ATP 15 CLP)

Regulation (EU) No. 2021/643 (ATP 16 CLP)

Restrictions related to the product or substances contained in accordance with Annex XVII of the Regulation (EC) 1907/2006 (REACH) as amended from time to time:

Restriction 3

Restriction 40

Restrictions on Contained Substances: Restriction 70

Restriction 75

Provisions relating to EU Directive 2012/18 (Seveso III):Seveso III category in accordance with Annex 1, Part 1

No

Substances subject to the export notification requirement Reg. (EC) 649/2012: None.

California Proposition 65

Substances listed in California Proposition 65: Cristobalite – Classified as carcinogenic.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the mixture Substances for which a chemical safety assessment has been carried out:

No

HEADING 16 — Other information

Hazard class and hazard category	Code	Description
Flam. Liq. 3	2.6/3	Flammable liquid, Category 3
Repr. 2	3.7/2	Reproductive toxicity, Category 2
STOT RE 1	3.9/1	Specific toxicity to specific target organs —Repeated exposure STOT rep., Category 1
Aquatic Chronic 1	4.1/C1	Chronic (long-term) danger to the aquatic environment, Category 1
Aquatic Chronic 3	4.1/C3	Chronic (long-term) aquatic hazard, Category 3

Classification and procedure used to establish the classification of mixtures in accordance with Regulation (EC) 1272/2008 [CLP]:

Classification in accordance with Regulation (EC) No	Classification Method
Aquatic Chronic	According to Article 12 of the CLP Regulation "Where, as a result of the assessment carried out in accordance with Article 9, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification: [...] (b) where conclusive scientific experimental data show that the substance or mixture is not biologically available and that the adequacy and reliability of those data has been established; [...]". Following a release study of D4 using the OECD 29 test on polymeric products representative of the amount of D4, the limit that would result in classification for chronic aquatic toxicity (NOEC of 0.0044 mg/L for fish and 0.0079 mg/L for aquatic invertebrates) is not met.

This document has been prepared by a competent person who has been appropriately trained.

Main bibliographical sources:

ECHA – European Chemical Agency

GESTIS - Information system on hazardous substances of the German Social Accident Insurance
IARC – International Agency for Research on Cancer
IPCS INCHEM – International Programme on Chemical Safety
ISS – Istituto Superiore di Sanità
PubChem - open chemistry database at the National Institutes of Health (NIH)

A safety data sheet is not required for this product in accordance with Article 31 of Regulation 1907/2006/EC. This safety data sheet has been created on a voluntary basis.

The information contained is based on our knowledge as of the date reported above. They refer only to the product indicated and do not constitute a guarantee of any particular quality. The user must ensure that this information is consistent and complete with respect to the specific use he or she must make of it. This sheet cancels and replaces any previous edition.

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

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

CLP: Classification, labelling, packaging.

DNEL: Derived level with no effect.

EINECS: European Inventory of Existing Commercial Chemicals.

And: Acute toxicity estimate, ATE ETAmix:
Acute Toxicity Estimation (Mixtures)

Hazardous Substances Ordinance: Ordinance on Dangerous Substances, Germany.

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

IATA: International Air Transport Association.

IATA-DGR: Regulations for the transport of dangerous goods 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 Dangerous Goods Code. PEARL: International Nomenclature of Cosmetic Ingredients.

KSt: Coefficient d'explosion.

LC50: Lethal concentration for 50 percent of the tested population.

LD50: Lethal dose for 50 percent of the population tested.

NECPs: Predicted no-effect concentration.

RID: Regulations concerning the international carriage of dangerous goods by rail.

SET: Short-term exposure limit.

STOT: Specific toxicity to specific target organs. TLV: Cut-off value

TWA: Time-weighted average WGK: German water hazard class.