

Safety data sheet

According to Annex II to REACH - Regulation 2015/830

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: **VESTIGE IMPLA CLEAR**

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

Dentistry – Elastomeric impression materials – ISO 4823:2015 Medical Device Directive 93/42/EEC
(Class I)

	Professional use	
<i>Dental medical device</i>	SU:	10
	ERC:	2, 3
	PROC:	1, 3, 5
	PC:	32.

1.3 Details of the supplier of the safety data sheet

Name: **TRAYART s.r.l.**

Full address: Via Paiette, 13/Q
35040 – Castelbaldo (PD) ITALY

+39 0425-546515
www.trayart.it

E-mail address of the competent person responsible for the Safety Data Sheet: info@trayart.it

1.4 Emergency telephone number

For urgent inquiries please refer to

- TRAYART s.r.l. – 0425-546515 (from Monday to Friday: 8.00-12.30 e 14.00-17.30)
- Austria +43 1 31304 5620
- Belgium +32022649636
- Bulgaria +359 2 9154 409
- Croatia +38514686917
- Cyprus +35722405611
- Czech Republic
- Denmark
- Estonia +3726943884
- Finland +358 5052 000

- France + 33 3 83 85 21 92
- Germany +302106479250/+302106479450
- Hungary not available
- Iceland +354 543 22 22
- Ireland +35318092566
- Latvia +371 67032600
- Liechtenstein no data available
- Lithuania +370 70662008
- Luxembourg +352 24785551
- Malta +356 2395 2000
- Netherlands +31 88 75 585 61
- Norway +4573580500
- Poland +48 42 2538 400
- Portugal +351213303271
- Romania +40213183606
- Slovakia +421 2 5465 2307
- Slovenia +38614006051
- Spain +34 917689800
- Sweden +46104566750
- United Kingdom +44 121 507 4123
- Switzerland/Conf. Suisse/Schweizerische Eidgenossenschaft/Conf. Svizzera 145
- USA - Poison Control Center - (800) 222-1222

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture.

The product is classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.1.1 Regulation 1272/2008 (CLP) and following amendments and adjustments.

Hazard classification and indication:

H372 Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements

2.3 Other hazards.

This product does not contain more than 0,1% PBT or vPvB substances.

SECTION 3. Composition/information on ingredients

3.2 Mixtures

Contains:

Identification	x = conc. %	Classification 1272/2008 (CLP)
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QUARTZ

CAS	14808-60-7	
CE	238-878-4	54 ≤ x < 58
INDEX	-	

STOT RE 1 H372

DIATOMACEOUS EARTH, SODA ASH FLUX CALCINATED

CAS	68855-54-9	
CE	272-489-0	5 ≤ x < 6
INDEX	-	

STOT RE 2 H373

Nr. Reg 01-2119488518-22-XXXX

SILICON DIOXIDE, GLASS, CHEMICALS

CAS	65997-17-3	
CE	266-046-0	5 ≤ x < 6
INDEX	-	

Substance with an occupational exposure limit

PLATINUM, 1,3-DETHYL-1,1,3,3-TETRAMETHYLDISILOXANE CPC

CAS	68478-92-2	
CE	270-844-4	0,35 ≤ x < 0,4
INDEX	-	

Flam. Liq. 2 H225, Aquatic Chronic 4 H413

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures**4.1 Description of first aid measures**

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

4.2 Most important symptoms and effects, both acute and delayed

For symptoms and effects caused by the contained substances, see chap. 11.

4.3 Indication of any immediate medical attention and special treatment needed

Information not available.

SECTION 5. Firefighting measures**5.1 Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2 Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

5.3 Advice for firefighters.**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal firefighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2 Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3 Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material. Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4 Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage**7.1 Precautions for safe handling**

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat. Avoid leakage of the product into the environment.

7.2 Conditions for safe storage, including any incompatibilities

Store only in the original container. Store in a well-ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

7.3 Specific end use(s)
Information not available.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters.

Regulatory references

CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	TRGS 900 (Fassung 31.1.2018 ber.) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2017
EST	Eesti	Töökeskkonna keemiliste ohutegurite piinormid 1. Vastu võetud 18.09.2001 nr 293 RT I 2001, 77, 460 - Redaktsiooni jõustumise kp: 01.01.2008
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GNR	United Kingdom	EH40/2005 Workplace exposure limits
NLD	Nederland	Databank of the social and Economic Concil of Netherlands (SER) Values, AF 2011:18
POL	Polska	ROZPORZĄDZENIE MINISTRA RODZIN Y, PRAC Y I POLITYKI SPOŁECZNEJ z dnia 12 czerwca 2018 r
SVN	Slovenija	Uradni list Republike Slovenije 04.06.2015 (1602) - Pravilnik o spremembah in dopolnitvah
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
EU	OEL EU	Direttiva (UE) 2017/2398; Direttiva (UE) 2017/164; Direttiva 2009/161/UE; Direttiva 2006/15/CE; Direttiva 2004/37/CE; Direttiva 2000/39/CE; Direttiva 91/322/CEE.
	TLV-ACGIH	ACGIH 2018
	RCP TLV	ACGIH TLVs and BEIs – Appendix H

QUARTZ

Threshold Limit Value					
Type	Country	TWA/8h mg/m ³	ppm	STEL/15min mg/m ³	ppm
TLV	CZE	0,1			
MAK	DEU	0,15			
VLA	ESP	0,05			
TLV	EST	0,1			
VLEP	FRA	0,1			RESP
WEL	GBR	0,3			
OEL	NLD	0,075			RESP
NDS	POL	0,1			INHAL
NDS	POL	0,1			RESP
MV	SVN	0,15			RESP
MAK	SWE	0,1			RESP
TLV-ACGIH		0,025			

DIATOMACEOUS EARTH, SODA ASH FLUX CALCINATED

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm		
RCP		4				RESP	Respirable dust
TLV							

Predicted no-effect concentration - PNEC

Reference value for STP microorganisms

100 mg/l

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Cute systemic	Chronic local	Chronic systemic
Oral								
Inhalation			VND				VND	0,05 mg/m3

SILICON DIOXIDE, GLASS, CHEMICALS

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm	
OEL	EU	5				INHAL

PLATINUM, 1,3-DETHYL-1,1,3,3-TETRAMETHYLDISILOXANE CPC

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm
OEL	EU	0,002			

Legend:

(C) = CEILING; INHAL = Inhalable Fraction; RESP = Respirable Fraction; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available; NEA = no exposure expected; NPI = no hazard identified.

8.2 Exposure controls

As the use of adequate technical equipment must always take priority over personal protection equipment, make sure that the workplace is well aired through effective local aspiration. Personal protection equipment must comply with the rules in force indicated below.

HAND PROTECTION

Protect hands with category II (ref. Directive 89/686/EEC and standard EN 374) work gloves, such as those in PVC, neoprene, nitril or equivalent. The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves` limit depends on the duration of exposure.

EYE PROTECTION

Wear protective airtight goggles (ref. standard EN 166).

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN 344). Wash body with soap and water after removing overalls.

RESPIRATORY PROTECTION

If the threshold value (if available) for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company`s prevention and protection service is exceeded, wear a mask with an A or universal filter, the class (1, 2 or 3) of which must be chosen according to the limit concentration of use (ref. standard EN 141).

The use of respiratory tract protection equipment, such as masks like that indicated above, is necessary to reduce worker exposure in the absence of technical measures. The protection provided by masks is in any case limited.

If the substance in question is odourless or its olfactory threshold is higher than the relative exposure limit and in the event of an emergency, or when exposure levels are unknown or the concentration of oxygen in the workplace is less than 17% volume, wear self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137) or fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece (ref. standard EN 138).

An emergency eye washing and shower system must be provided.

The product must be used in well-aired environments fitted with strong localised aspiration systems, otherwise to use the personal protection equipment indicated.

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism; consequently, personal protective equipment must be managed so as to guarantee maximum protection (e.g. by reducing the replacement times for used PPE).

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties**Property**

Appearance	Viscous fluid
Colour	None
Odour	None
Odour threshold	Not available
pH	Not available
Melting point / freezing point	Not available
Initial boiling point	Not available
Boiling range	Not available
Flash point	> 161° C
Evaporation Rate	Not available
Flammability (solid, gas)	Not available
Upper inflammability limit	Not available
Lower inflammability limit	Not available
Upper explosive limit	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	Not available
Solubility	Not available
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidising properties	Not available

9.2. Other information

Information not available.

SECTION 10. Stability and reactivity**10.1 Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

10.2 Chemical stability

The product is stable in normal conditions of use and storage.

10.3 Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

10.4 Conditions to avoid

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

10.5 Incompatible materials

Information not available.

10.6 Hazardous decomposition products

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification. It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

This product must be handled carefully because of its possible teratogenic effects, which may be toxic and damage the foetus development.

This product may cause functional disorders or morphological mutations after repeated or prolonged exposure and/or may accumulate inside the human body and is thus graded as dangerous.

Acute effects: stinging eyes. Symptoms may include: rubescence, edema, pain and lachrymation.

Vapour inhalation may moderately irritate the upper respiratory tract. Contact with skin may cause slight irritation. Ingestion may cause health problems, including stomach pain and sting, nausea and sickness.

11.1 Information on toxicological effects

DIATOMACEOUS EARTH, SODA ASH FLUX CALCINATED

LD50 (Oral) >2000 mg/kg rat

LC50 (Inhalation) >2,6 mg/l/4h rat

SILICON DIOXIDE, GLASS, CHEMICALS

LD50 (Oral) 5000 mg/kg

POLYDIMETHYLSILOXANE VINYL TERMINATED

LD50 (Oral) >15440 mg/kg rat

LD50 (Dermal) >15440 mg/kg rabbit

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation.

12.1 Toxicity

Information not available

12.2 Persistence and degradability

Information not available

12.3 Bioaccumulative potential

Information not available

12.4 Mobility in soil

Information not available

12.5 Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6 Other adverse effects

Information not available.

SECTION 13. Disposal considerations**13.1 Waste treatment methods**

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. Avoid littering. Do not contaminate soil, sewers and waterways.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not to be considered dangerous according to the provisions in force on the transport of dangerous goods by road (A.D.R.), by rail (RID), by sea (IMDG Code) and by air (IATA)

14.1 UN number

Not available

14.2 UN proper shipping name

Not available

14.3 Transport hazard class(es)

Not available

14.4 Packing group

Not available

14.5 Environmental hazards

Not available

14.6 Special precautions for user

Not available

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not available

SECTION 15. Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso category: none.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product: point 3 - 40

Substances in Candidate List (Art. 59 REACH): On the basis of available data, the product does not contain SVHC substances in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH): none.

Substances subject to exportation reporting pursuant to (EC) Reg. 689/2008: none.

Substances subject to the Rotterdam Convention: none.

Substances subject to the Stockholm Convention: none.

Healthcare controls: Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2 Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 2 Flammable liquid, category 2

Flam. Liq. 3	Flammable liquid, category 3
STOT RE 1	Specific target organ toxicity - repeated exposure, category 1
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Aquatic Chronic 4	May cause long lasting harmful effects to aquatic life.
H225	Easily flammable liquid and vapour.
H226	Flammable liquid and vapour.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure
H413	May cause damage to aquatic organisms with long-term effects.

Use descriptors

ERC	2	Formulation into mixture
ERC	3	Formulation into solid matrix
PC	32	Polymer preparations and compounds
PROC	1	Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.
PROC	3	Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
PROC	5	Mixing or blending in batch processes
SU	10	Formulation [mixing] of preparations and/or re-packaging (excluding alloys)

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds

- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation.

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.