



PREVEST DENPRO LIMITED

Reg. Office : 38, Industrial Estate, Digiana, Jammu-180010, India
Unit II, EPIP, Bari Brahmana, Jammu-181133, India
Phones : +91 1923 222774, 222779, Fax : 222779
Web : www.prevestdenpro.com, E-mail : info@prevestdenpro.com

MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name: Hiflex Silky Touch Bite Registration
INTENDED USE: Dental Impression Material
Company Name: Prevest Denpro Limited
Address: 38, Industrial Estate, Digiana, Jammu-180010 (India)
Tel: + 91-191-2430442
Fax No. +91-191-2430442
Email: info@prevestdenpro.com
Web: www.prevestdenpro.com
Emergency Contact No:- +91-191-2432548

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Chemical characterisation: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 14464-46-1	cristobalite	STOT RE 1, H372	50-100%
EINECS: 238-455-4			
CAS: 14808-60-7	Quartz (SiO ₂)	STOT RE 1, H372	10-<25%
EINECS: 238-878-4			

Additional information: For the wording of the listed risk phrases refer to section 16.

SECTION 3: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms GHS08

Signal word Danger

Hazard-determining components of labelling:

cristobalite

Quartz (SiO₂)

Hazard statements

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

Precautionary statements

P314 Get medical advice/attention if you feel unwell.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.



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Additional information:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation : Supply fresh air; consult doctor in case of complaints.

After skin contact:

Immediately rinse with water.

If skin irritation continues, consult a doctor.

After eye contact : Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing : Seek medical treatment.

4.2 Most important symptoms and effects,

both acute and delayed : No further relevant information available.

4.3 Indication of any immediate medical

attention and special treatment needed : No further relevant information available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents : CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from

the substance or mixture : No further relevant information available.

5.3 Advice for firefighters

Protective equipment : No special measures required.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures Not required.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up: Pick up mechanically.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Only adequately trained personnel should handle this product.



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For use in dentistry only.

Information about fire - and explosion protection : No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: Store only in the original receptacle.

Information about storage in one common storage facility: Not required.

Further information about storage conditions:

Keep container tightly sealed.

Protect from heat and direct sunlight.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical facilities: No further data; see item 7.

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

Usual hygienic measures for dental practice.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Respiratory protection: Not required.

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Safety glasses

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES



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9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form	:	Viscous
Colour	:	Different according to colouring
Odour	:	like peppermint
Odour threshold	:	Not determined.
pH-value	:	Not applicable.

Change in condition

Melting point/Melting range	:	Undetermined.
Boiling point/Boiling range	:	Undetermined.
Flash point	:	Not applicable.
Flammability (solid, gaseous)	:	Not applicable.
Self-igniting	:	Product is not selfigniting.
Danger of explosion	:	Product does not present an explosion hazard.
Explosion limits:		
Lower	:	Not determined.
Upper	:	Not determined.
Vapour pressure	:	Not determined.
Density at 20 °C	:	1.0 - 1.6 g/cm ³
Relative density	:	Not determined.
Vapour density	:	Not determined.
Evaporation rate	:	Not determined.
Solubility in / Miscibility with Water	:	Nearly insoluble.
Partition coefficient (n-octanol/water):	:	Not determined.
Viscosity:		
Dynamic	:	Not determined.
Kinematic	:	Not determined.
9.2 Other information	:	No further relevant information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	:	No further relevant information available.
10.2 Chemical stability	:	Stable under normal handling and storage conditions.
Thermal decomposition / conditions to be avoided	:	No decomposition if used according to specifications.
10.3 Possibility of hazardous reactions	:	No dangerous reactions known.
10.4 Conditions to avoid	:	No further relevant information available.
10.5 Incompatible materials	:	No further relevant information available.
10.6 Hazardous decomposition Products	:	None under normal conditions of storage and use.



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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

Primary irritant effect:

on the skin : No irritant effect.
on the eye : No irritating effect.
Sensitisation : No sensitising effects known.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity : No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil : No further relevant information available.

Additional ecological information:

General notes : Water hazard class 1 (German Regulation) (Self-assessment):
slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach
ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations

SECTION 14: TRANSPORT INFORMATION

14.1 UN-Number

ADR, ADN, IMDG, IATA Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA Void



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14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class Void

14.4 Packing group

ADR, IMDG, IATA Void

14.5 Environmental hazards:

Marine pollutant : No

14.6 Special precautions for user Not applicable.

4.7 Transport in bulk according to Annex II of

MARPOL73/78 and the IBC Code Not applicable.

Transport/Additional information : Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

SECTION 15: REGULATORY INFORMATION

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

National regulations:

Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.