

SECTION 1: Identification of the substance/preparation and of the company/undertaking

1.1- Product Identification

Product Name : Ad Sil Acura Hard Set Putty Base
Product Code : ASH
Product Description : Addition silicone impression material
Packing Available : 250ml

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

Relevant identified uses : Addition silicone dental impression material. Used by dental professional only.
For dental use only.

1.3- Details of the supplier of the safety data sheet

Manufacturer : Prime Dental Products Pvt Ltd.
Address : Plot No. A-148, Road No. 24, MIDC, Wagle Industrial Estate, Thane (West)-
400604, Maharashtra, India
Email : info@prime-dental.in
Web : www.prime-dental.in

1.4- Emergency contact details

Telephone : +919272235922 / +919272235925

SECTION 2: Composition/information on ingredients

2.1- Mixture

Component	C.A.S.	EINECS	Classification*	Weight%	LD50
Cristobalite	14464-46-1	NA	Community workplace exposure limit	40-80	Ingestion-Rat: >5,000 mg/kg
Vinyl siloxane	68083-19-2	NA	NA	20-40	Ingestion-Rat: >15,440 mg/kg
Dimethyl hydrogen siloxane	68037-59-2	NA	NA	1-10	Ingestion-Rat: >2,000 mg/kg

*For wording of the listed 'R' phrases and 'H' statements see section 16

SECTION 3: Identification of Hazards

3.1- Hazard Description : Not Applicable

3.2- Information concerning to particular hazards to man and environment

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

3.3- Classification system

The classification is according to the latest editions of the EU-lists and extended by company and literature data.

SECTION 4: First aid measures

4.1- Description of first aid measures

Contact with skin: Wash with soap and water. Get medical attention if irritation develops or persists.

Contact with eyes: Flush eyes with plenty of water. Get medical attention, if irritation persists.

Ingestion: Rinse mouth. Consult a physician if ingested in large amounts.

Inhalation: Supply fresh air. Get medical attention if uncomfortable

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: Water or foam

5.2- Extinguishers not to be used: None in particular.

5.3- Risks arising from combustion: Avoid inhaling the fumes. During combustion carbon monoxide, carbon dioxide, or irritant gases may be released.

5.4- Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental Release Measures

6.1 Measures for personal safety: None in particular

6.2 Measures for environmental protection: Do not allow product to reach sewage system or any water courses.

6.3 Measures for cleaning/collecting: Recover the product for re-use if possible, or for elimination. The product may, where appropriate, be absorbed by inert material. After the product has been recovered, rinse the area and materials involved with water.

SECTION 7: Handling and Storage

7.1-Handling product: Is intended for dental use only.

7.2- Information for safe handling: No special measures required. Observe normal care for working with chemicals.

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

7.4- Storage requirements to be met by storerooms and receptacles: Store only in the original receptacle.

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

7.6- Further information about storage conditions: Protect from heat and direct sunlight. Store away from acids, strong bases, oxidizing agents and amines.

SECTION 8: Exposure Controls/Personal Protection

8.1- Additional information about design of technical facilities: No further data; see section 7.

8.2- Ingredients with limit values that require monitoring at the workplace: Cristobalite

ACGIH - TWA (respirable): 0.025 mg/m³

OSHA - TWA (respirable): 0.15 mg/m³

8.3- Personal protective equipment:

a. Respiratory protection : Not required.

b. 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.

c. Eye protection : Not required

d. Body protection : Not required

SECTION 9: Physical and Chemical Properties

9.1- Physical Properties:

Form : Solid paste

Color : Blue

Odour : None

9.2- Chemical Properties:

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Ignition temperature : Undetermined

Flash point : >93°C

Self-igniting : Product is not self-igniting.

Danger of explosion : Undetermined.

Density : 1.3-1.8 g/cm³

Solubility in / Miscibility with Water : Negligible

SECTION 10: Stability and Reactivity

10.1- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications. Avoid acids, strong bases, oxidizing agents and amines.

Product Name: AD SIL ACURA HARD SET
PUTTY

10.2- Dangerous reactions: No dangerous reactions known

10.3 Dangerous decomposition products: No dangerous decomposition products known

SECTION 11: Stability and Reactivity

11.1- Acute toxicity-

Cristobalite LD50: Ingestion (Rat) : >5,000 mg/kg
Vinyl siloxane LD50: Ingestion (Rat) : >15,440 mg/kg
Dimethyl hydrogen siloxane: Ingestion (Rat) : >2,000 mg/kg

11.2- Primary irritant effect : Nil

11.3- On swallowing : Gastrointestinal irritation.

11.4- On inhalation : No known effects

11.5- Sensitization : No sensitizing effects known.

SECTION 12: Ecological Information

12.1- Environmental data: No data available. Contact Env. Dept.

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

13.2- Uncleaned Packaging Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport Information

14.1- Air (ICAO/IATA)

Primary Hazard Class/Division : No classification

14.2- Road (RID/ADR)

Primary Hazard Class/Division : No classification

14.3- Vessel (IMO/IMDG/RID/ADR)

Primary Hazard Class/Division : No classification

SECTION 15: Regulatory Information

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

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2- Chemical safety assessment : See Section 11

SECTION 16: Additional Information

16.1- 'R' phrases and 'H' statement: None

16.2- Prepared by: Tanay Thakkar

16.3- Manufacturer Disclaimer: For Dental Use Only, Use as directed.

The information and recommendations are taken from sources (raw material MSDS(s) and manufacturer's knowledge) believed to be accurate; however, Prime Dental Products Pvt Ltd, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.

SECTION 1: Identification of the substance/preparation and of the company/undertaking

1.1- Product Identification

Product Name : Ad Sil Acura Hard Set Putty Catalyst
Product Code : **AHS**
Product Description : Addition silicone impression material
Packing Available : 250ml

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

Relevant identified uses : Addition silicone dental impression material. Used by dental professional only.
For dental use only.

1.3- Details of the supplier of the safety data sheet

Manufacturer : Prime Dental Products Pvt Ltd.
Address : Shree Arihant Compound, Bldg #E-8, Gala #7-10, Thane Bhiwandi Road, village Kalher, Taluka Bhiwandi, Dist Thane 421302, India.
Email : info@prime-dental.com
Web : www.prime-dental.com

1.4- Emergency contact details

Telephone : +919272235922 / +919272235925

SECTION 2: Composition/information on ingredients

2.1- Mixture

<u>Component</u>	<u>C.A.S.</u>	<u>EINECS</u>	<u>Classification*</u>	<u>Weight%</u>	<u>LD50</u>
Cristobalite	14464-46-1	NA	Community workplace exposure limit	40-80	Ingestion-Rat: >5,000 mg/kg
Vinyl siloxane	68083-19-2	NA	NA	20-40	Ingestion-Rat: >15,440 mg/kg

*For wording of the listed 'R' phrases and 'H' statements see section 16

SECTION 3: Identification of Hazards

3.1- Hazard Description : Not Applicable

3.2- Information concerning to particular hazards to man and environment

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

3.3- Classification system

The classification is according to the latest editions of the EU-lists and extended by company and literature data.

SECTION 4: First aid measures

4.1- Description of first aid measures

Contact with skin: Wash with soap and water. Get medical attention if irritation develops or persists.

Contact with eyes: Flush eyes with plenty of water. Get medical attention, if irritation persists.

Ingestion: Rinse mouth. Consult a physician if ingested in large amounts.

Inhalation: Supply fresh air. Get medical attention if uncomfortable

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: Water or foam

5.2- Extinguishers not to be used: None in particular.

5.3- Risks arising from combustion: Avoid inhaling the fumes. During combustion carbon monoxide, carbon dioxide, or irritant gases may be released.

5.4- Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental Release Measures

6.1 Measures for personal safety: None in particular

6.2 Measures for environmental protection: Do not allow product to reach sewage system or any water courses.

6.3 Measures for cleaning/collecting: Recover the product for re-use if possible, or for elimination. The product may, where appropriate, be absorbed by inert material. After the product has been recovered, rinse the area and materials involved with water.

SECTION 7: Handling and Storage

7.1-Handling product: Is intended for dental use only.

7.2- Information for safe handling: No special measures required. Observe normal care for working with chemicals.

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

7.4- Storage requirements to be met by storerooms and receptacles: Store only in the original receptacle.

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

7.6- Further information about storage conditions: Protect from heat and direct sunlight. Store away from acids, strong bases, oxidizing agents and amines.

SECTION 8: Exposure Controls/Personal Protection

8.1- Additional information about design of technical facilities: No further data; see section 7.

8.2- Ingredients with limit values that require monitoring at the workplace: Cristobalite

ACGIH - TWA (respirable): 0.025 mg/m³

OSHA - TWA (respirable): 0.15 mg/m³

8.3- Personal protective equipment:

a. Respiratory protection : Not required.

b. 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.

c. Eye protection : Not required

d. Body protection : Not required

SECTION 9: Physical and Chemical Properties

9.1- Physical Properties:

Form : Solid paste

Color : White

Odour : None

9.2- Chemical Properties:

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Ignition temperature : Undetermined

Flash point : >93°C

Self-igniting : Product is not self-igniting.

Danger of explosion : Undetermined.

Density : 1.3-1.8 g/cm³

Solubility in / Miscibility with Water : Negligible

SECTION 10: Stability and Reactivity

10.1- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications. Avoid acids, strong bases, oxidizing agents and amines.

10.2- Dangerous reactions: No dangerous reactions known

10.3 Dangerous decomposition products: No dangerous decomposition products known

SECTION 11: Stability and Reactivity

11.1- Acute toxicity-

Cristobalite LD50: Ingestion (Rat) : >5,000 mg/kg
Vinyl siloxane LD50: Ingestion (Rat) : >15,440 mg/kg

11.2- Primary irritant effect : Nil

11.3- On swallowing : Gastrointestinal irritation.

11.4- On inhalation : No known effects

11.5- Sensitization : No sensitizing effects known.

SECTION 12: Ecological Information

12.1- Environmental data: No data available. Contact Env. Dept.

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

13.2- Uncleaned Packaging Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport Information

14.1- Air (ICAO/IATA)

Primary Hazard Class/Division : No classification

14.2- Road (RID/ADR)

Primary Hazard Class/Division : No classification

14.3- Vessel (IMO/IMDG/RID/ADR)

Primary Hazard Class/Division : No classification

SECTION 15: Regulatory Information

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

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2- Chemical safety assessment : See Section 11

SECTION 16: Additional Information

16.1- 'R' phrases and 'H' statement: None

16.2- Prepared by: Tanay Thakkar

16.3- Manufacturer Disclaimer: For Dental Use Only, Use as directed.

The information and recommendations are taken from sources (raw material MSDS(s) and manufacturer's knowledge) believed to be accurate; however, Prime Dental Products Pvt Ltd, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.
