

1. IDENTIFICATION OF SUBSTANCE / MIXTURE AND OF SUPPLIER

Product Identifier:

Trade Name: maxill Light Body, maxill Super Light Body, maxill Heavy Body, maxill Light Body HTS, maxill Monophase, maxill Alginate Free, maxill Bite Registration, maxill Putty, maxill Mono, maxill Bite Air Mixture

Product Form:

Application of the substance or the preparation:

Addition curing vinyl polysiloxane dental impression materials (consisting of Base & Catalyst)

Supplier Details:

CANADA

maxill inc.
80 Elm St.
St. Thomas, ON, Canada, N5R 6C8

USA

maxill inc.
500 W. Main Street
Cortland, OH
44410

Emergency Contact: maxill inc. 519-631-7370

24 hours: In Canada, CANUTEC: 613-996-6666

In USA/Canada, ChemTel: 1-800-255-3924, outside USA/Canada 1-813-248-0585

2. HAZARDS IDENTIFICATION

GHS label elements, including precautionary statements



Signal Word:

WARNING

Hazard statement(s)

H317

May cause an allergic skin reaction.

H319

Causes serious eye irritation.

Precautionary statement(s)

P264

Wash hands thoroughly after handling.

P280

Wear protective gloves and eye and face protection.

P272

Contaminated work clothing should not be allowed out of the workplace.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

| CAS | Material | % w/w |
|------------|---------------------------------------|---------|
| 68083-19-2 | Polydimethylsiloxane vinyl terminated | 20 – 40 |
| 68037-59-2 | Dimethylsiloxane copolymer | 1 – 10 |
| 14808-60-7 | Quartz silica | 30 – 50 |
| 27306-78-1 | Polysiloxane | < 5 |

4. FIRST AID MEASURES

Description of first aid measures

After inhalation

Remove person to fresh air. Get medical attention if you feel unwell.

After contact with skin

Immediately flush with water and then wash with soap and water. In case skin irritation persists, get medical attention.

After contact with eyes

Rinse with copious amounts of water for at least 15 minutes. Get medical attention.

After ingestion

Flush mouth with water and get medical attention.

Further information

None

5. FIRE FIGHTING MEASURES

Suitable extinguishing media

Water spray, foam, carbon dioxide, dry chemicals depending on the materials involved in the fire.

Extinguishing media to avoid

Not known.

Special hazards arising from combustion

No relevant information is available for this product.

Special protective equipment for fire-fighters

No special measures are required.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Ventilate area. Avoid contact with skin and eyes.

Environmental precautions

Do not allow to enter sewers or ground water

Methods for cleaning up/collecting

Collect mechanically. The product may be absorbed by liquid-binding material (sand, diatomite, acid binders).

7. HANDLING AND STORAGE

Precautions for safe handling

Adequately trained personnel should handle this product. Do not eat, drink or smoke when using the product. Wash thoroughly after handling. Contaminated clothing should not be allowed out of the workplace and in any case it should be washed before reuse. Keep container tightly closed.

Precautions in case of fire and explosion

Extinguish all sources of ignition. No special measures required.

Conditions for safe storage, including any incompatibilities

Store product in a cool and dry place. Avoid direct sunlight, strong bases, acids, oxidizing agents and amines. Store in the original container

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Occupational exposure limits

In case a component is shown in section 3 but it does not appear in the table below, there are not any available data for this component.

| C.A.S. No. | Component | Agency | Limit |
|------------|---------------|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 14808-60-7 | Quartz silica | ACGIH | TWA: 0.025* mg/m ³ *respirable fraction |
| 14808-60-7 | Quartz silica | OSHA | TWA: 0.3* mg/m ³ *concentration as a total of dust TWA: 0.1* mg/m ³ (2.4 millions of particles/cu. ft.) *concentration respirable |

ACGIH: American Conference of Government Industrial Hygienists
OSHA: United States Department of Labour – Occupational Safety and Health Administration
TWA: Time-Weighted-Average

Exposure control

Personal protective equipment (PPE)

| | |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Ventilation: | Ensure adequate ventilation of the premises where the product is stored and/or handled. |
| Respiratory protection: | Not required. |
| Hand protection: | Suitable protective gloves may be worn. The use of vinyl gloves is suggested. (Setting time of polyvinylsiloxanes is inhibited by latex gloves). |
| Eye protection: | Safety goggles are recommended. |
| Skin protection: | Do not eat, drink or smoke when using the product. |
| Other: | Lab coat is suggested when using the product. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---------------------------------------------------|--------------------------------------|
| Appearance (<i>physical state, color, etc.</i>) | Bio-component pastes/viscous liquids |
| Odor | Characteristic |
| Odour threshold | Not available |
| pH value | Not applicable |
| Melting point | Not applicable |

| | |
|---------------------------|------------------------------|
| Boiling point | Not applicable |
| Flash point | Not applicable |
| Evaporation rate | No data available |
| Flammability (solid, gas) | Not applicable |
| Density | 1,2-1,8 g/cm ³ |
| Vapour pressure | Not applicable |
| Vapour density | Not applicable |
| Viscosity | Not determined |
| Solubility | Insoluble in water |
| Auto ignition | Product is not self-igniting |
| Flash point | No flash point |
| Boiling point | Not applicable |
| Viscosity | No data available |

10. STABILITY AND REACTIVITY

Reactivity

No relevant information available.

Chemical stability

Stable under normal storage and handle conditions.

Hazardous decomposition products

None, if used in accordance with instructions.

Conditions to avoid

No relevant information available, if used in accordance with instructions.

Possibility of hazardous reactions

None, if used in accordance with instructions.

11. TOXICOLOGICAL INFORMATION

It is required by the U.S. OSHA Hazard Communication Standard to include all the known hazards of the product or components included regardless the potential risk.

All the information presented below corresponds to the uncured components included in the product.

Once the product is mixed according to the instructions for use it is safe for its intended use.

Information on toxicological effects

Inhalation: No adverse health effects are expected.

Skin contact: May cause mild irritation.

Eye contact: May cause irritation.

Ingestion: There is a possibility of gastrointestinal irritation with the symptoms being stomach pain and upset, nausea, diarrhoea and vomiting.

Additional toxicological information

Carcinogenicity:

During normal / intended use it is not expected to cause the following health effect(s) during exposure

| C.A.S. No. Component | Class description | Regulation |
|--------------------------|-----------------------|-------------------------------------------------------|
| 14808-60-7 Quartz silica | Group 1: Carcinogenic | International Agency for Research on Cancer to humans |

Toxicological data:

In case a component is shown in section 3 but it does not appear in the table below, there are not any

**Silicone Impression Material
SAFETY DATA SHEET**



available data for this component.

Acute Toxicity

| Polydimethylsiloxane vinyl terminated | | |
|----------------------------------------------|-------------|----------------|
| Dermal | Rabbit LD50 | > 15,440 mg/Kg |
| Ingestion | Rat LD50 | > 15,440 mg/Kg |
| Dimethylsiloxane copolymer | | |
| Dermal | Rabbit LD50 | > 2,000 mg/Kg |
| Ingestion | Rat LD50 | > 2,000 mg/Kg |
| Inhalation | Rat LC50 | 4.2 mg/L |
| Quartz silica | | |
| Dermal | LD50 | > 5,000 mg/Kg |
| Ingestion | LD50 | > 5,000 mg/Kg |
| Polysiloxane | | |
| Dermal | Rabbit LD50 | > 2,000 mg/Kg |
| Ingestion | Rat LD50 | > 2,000 mg/Kg |
| Inhalation | Rat LC50 | 2 mg/L |

Skin corrosion/irritation

| Polydimethylsiloxane vinyl terminated | |
|----------------------------------------------|---------------------------|
| Rabbit | Mild irritation |
| Quartz silica | |
| Rabbit | No significant irritation |
| Polysiloxane | |
| Rabbit | No significant irritation |

Serious eye damage/Irritation

| Polydimethylsiloxane vinyl terminated | |
|----------------------------------------------|-------------------|
| Rabbit | Mild irritation |
| Polysiloxane | |
| Rabbit | Severe irritation |

Skin sensitization

| Polydimethylsiloxane vinyl terminated | |
|----------------------------------------------|-----------------|
| Guinea pig | Not sensitizing |

Respiratory sensitization:

No available data for this component.

Germ cell mutagenicity

| Quartz silica | |
|----------------------|---------------|
| In vitro | Not mutagenic |
| Polysiloxane | |
| In vitro | Not mutagenic |

Carcinogenicity

| | |
|----------------------|-------------------------------|
| Quartz silica | |
| Inhalation | Human and Animal Carcinogenic |

Reproduced toxicity:

In case a component is shown in section 3 but it does not appear in the table below, there are not any available data for this component.

Reproduced and/or development effects

| Polysiloxane | | | |
|---------------------|---------------------------------------------------------------------------------|----------------|---------------------------------------------|
| Route | Target Organ/Value | Species | Test Result/Exposure Duration |
| Ingestion | There is evidence for positive reproduction but limited data for classification | Rat NOAEL | 450 mg/Kg/day pre-mating & during gestation |

Target organ(s):

No available data for this component.

Specific target organ toxicity – single exposure:

No available data for this component

Specific target organ toxicity – repeated exposure:

| Quartz silica | | | |
|----------------------|----------------------------------------------------------------------------|----------------|--------------------------------------|
| Route | Target Organ/Value | Species | Test Result/Exposure Duration |
| Inhalation | Silicosis - Causes damage to organs through prolonged or repeated exposure | Human NOAEL | Occupational exposure |

Aspiration hazard:

In case a component is shown in section 3 but it does not appear here, there are not any available data for this component.

12. ECOLOGICAL INFORMATION

If material is properly used and handled no ecological problems are to be anticipated
Do not discard material into drains/sewers or aquatic environment

13. DISPOSAL CONSIDERATIONS

Disposal must be carried out in accordance to the local and national regulations currently in force.

14. TRANSPORT INFORMATION

UN-Number

DOT, ADR, ADN, IMDG, IATA

None

UN proper shipping name

DOT, ADR, ADN, IMDG, IATA

None

Transport hazard class

MP-REF-53784S

DOT, ADR, ADN, IMDG, IATA
Class
None
Packing group
DOT, ADR, IMDG, IATA
None

15. REGULATORY INFORMATION

The product is not considered hazardous under D. Lgs. 65/03.
The product is a medical device according to EC directive 93/42/EEC
This product is classified as a medical device under US regulations and it has been reviewed by the US Food and Drug Administration (FDA)

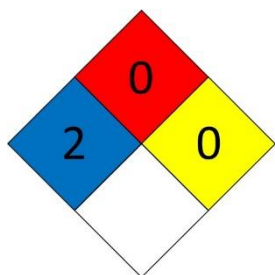
16. OTHER INFORMATION: INCLUDING INFORMATION ON PREPARATION AND REVISION OF THE SDS

CAUTION: PRODUCT FOR PROFESSIONAL USE ONLY

Disclaimer

maxill inc. believes that the information on this SDS was obtained from reliable sources. However, the information is provided without any warranty, expressed or implied, regarding its correctness. Some information presented and conclusions drawn herein are from sources other than direct test data on the substance itself. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, maxill Inc. does not assume responsibility and expressly disclaims liability for loss, damage, or expense arising out of or in any way connected with handling, storage, use, or disposal of this product. If the product is used as a component in another product, this SDS information may not be applicable. Information is correct to the best of our knowledge at the date of the SDS publication.

| | |
|---------------------|--------------------------------------------------------------------------------------------------------------------|
| NFPA health hazard: | 2 - Intense or continued but not chronic exposure could cause temporary incapacitation or possible residual injury |
| NFPA fire hazard: | 0 – Material will not burn under typical fire conditions |
| NFPA reactivity: | 0 - Normally stable, even under fire exposure conditions, and are not reactive with water. |



HMIS III Rating

| | |
|---------------|------------------------------------------------------------------|
| Health: | 2 Slight Hazard - Irritation or minor reversible injury possible |
| Flammability: | 0 Serious Hazard |
| Physical: | 0 Minimal Hazard |