

1: Identification

GHS Product identifier maxill Vinyl Polysiloxane Impression Material

Other means of identification

maxill Super Light Body, maxill Light Body, maxill Heavy Body, maxill Light Body HTS, maxill Monophase, maxill Alginate Free, maxill Bite Registration, maxill Putty

Recommended use of the chemical and restrictions on use

Substance is suitable to reproduce the structure of a patient's teeth and gums, or other oral anatomy.
Rx Only (FDA)

Supplier's details

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

Telephone: 1-800-268-8633, E-mail: info@maxill.com, Website: www.maxill.com

Emergency phone number (24h) CANUTEC: 1-888-CAN-UTEC (226-8832),

VelocityEHS* Accelerate Emergency Response Service (formerly ChemTel):
1-800-255-3924, outside US & Canada, 1-813-248-0585

2: Hazard identification

Classification of the substance or mixture Not classified.

Physical hazards None.

Health hazards Skin sensitization Category 1B
Serious eye damage/eye irritation Category 2/2A

Environmental hazards None.

WHMIS 2015 defined hazards Not classified.

GHS label elements including precautionary statements



Signal word WARNING

Hazard statement Causes serious eye irritation.
May cause an allergic skin reaction.

Precautionary statements

Prevention	Wash hands thoroughly after handling. Wear eye protection. Avoid breathing any dust or fumes. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves.
Response	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical help. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help. Specific treatment (see Section 4 of SDS). Take off contaminated clothing and wash it before reuse.
Storage	No special storage requirements.
Disposal	Dispose of contents/container in accordance with municipal, provincial/state, and federal regulations.

Other hazards which do not result in classification

WHMIS 2015: Health hazards not otherwise classified	Not applicable.
WHMIS 2015: Physical hazards not otherwise classified	Not applicable.

3: Composition/information on ingredients

CAS	Ingredient	Percent (%) w/w
68083-19-2	Polydimethylsiloxane vinyl terminated	15 - 40
68037-59-2	Dimethylsiloxane copolymer	5 - 10
14808-60-7	Quartz silica	30 - 60
27306-78-1	Polysiloxane	1 - 5

The actual concentration range is withheld as a trade secret.

4: First-aid measures

Description of necessary first-aid measures

Inhalation	Remove person to fresh air. If you feel unwell, get medical help.
Skin contact	Immediately flush with water and then wash with soap and water. In case skin irritation persists, get medical help.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical help.
Ingestion	If swallowed, do not induce vomiting. If vomiting occurs naturally, have victim lean forward to reduce risk of aspiration. Rinse mouth. Get medical help.

Most important symptoms/effects, acute and delayed None identified.

Indication of immediate medical attention and special treatment needed

If you feel unwell, seek medical advice, and show the label where possible. Ensure that first aid responders are aware of the material(s) involved and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Keep out of reach of children.

5: Fire-fighting measures

Suitable Extinguishing Media For the materials involved in a fire, use dry chemical, foam, water, or CO₂.

Unsuitable extinguishing media Not available.

Specific Hazards Arising from the Mixture

Fire Hazard	Not applicable.
Explosion Hazard	Not applicable.
Reactivity	Will not occur under normal conditions.

Special protective actions for fire-fighters None.

6: Accidental release measures

Personal precautions, protective equipment, and emergency procedures

Non-emergency personnel For accidental spills of this product, personal protective equipment is not normally required when handling the material. See Section 8 of the SDS.

Emergency responders For accidental spills of this product, personal protective equipment is not normally required when handling the material. See Section 8 of the SDS.

Environmental precautions Not applicable.

Methods and materials for containment and cleaning up This product is compatible with all glove materials (PPE). There are no inappropriate containment measures of clean up processes.

7: Handling and storage

Precautions for safe handling Observe good chemical hygiene practices. Trained personnel should handle this product. Do not eat, drink, or smoke when using this product. Keep container tightly closed.

Conditions for safe storage, including any incompatibilities Keep in original container. Keep away from food, drink, and animal feed. Avoid direct sunlight, strong bases/acids/oxidizing agents/amines. Keep at room temperature.

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.

<u>C.A.S. No.</u>	<u>Component</u>	<u>Agency</u>	<u>Limit</u>
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 million 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

Appropriate engineering controls Not normally required.

Individual protection measures, such as personal protective equipment (PPE) Not normally required.

Eye/face protection Safety glasses.

Skin protection Vinyl or nitrile gloves are recommended. Setting time of material is inhibited by latex gloves. Lab coat is recommended to be worn.

Respiratory protection Not normally required.

Thermal hazards Not applicable.

9: Physical and chemical properties and safety characteristics

Physical state	Biocomponent pastes/viscous liquids
Colour	Various
Odour	Characteristic
Melting point / freezing point	Not available (N/Av)
Boiling point	Not applicable (N/Ap)
Flammability	N/Ap
Lower and upper explosion limit / flammability limit	N/Av
Flash point	N/Ap

Auto-ignition temperature	Product is not self-igniting
Decomposition temperature	N/Av
pH	N/Av
Kinematic viscosity	N/Av
Solubility	Insoluble in water
Partition coefficient: <i>n</i> -octanol/water (log value)	N/Av
Vapour pressure	N/Av
Density or specific gravity	1.2 – 1.8 g/cm ³
Relative vapour density	N/Av
Particle characteristics	N/Ap

10: Stability and reactivity

Reactivity Not reactive under normal conditions.

Chemical stability Stable under normal storage, handling, and transportation.

Possibility of hazardous reactions Hazardous reactions will not occur under normal conditions.

Conditions to avoid Avoid extremely high or freezing temperatures to maintain product integrity.

Incompatible materials None.

Hazardous decomposition products None.

11: Toxicological information

Information on the likely routes of exposure

Ingestion Gastrointestinal irritation is not expected, but may cause stomach distress, nausea, or vomiting.

Skin contact May cause mild irritation.

Eye contact Causes serious eye irritation.

Inhalation None expected.

Symptoms related to the physical, chemical, and toxicological characteristics Not available.

Delayed and immediate effects and also chronic effects from short- and long-term exposure Not available.

Numerical measures of toxicity

Carcinogenicity:

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

<u>CAS</u>	<u>Component</u>	<u>Class description</u>	<u>Regulation</u>
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 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
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Ingestion	Rat LD50	> 2,000 mg/Kg
Inhalation	Rat LC50	4.2 mg/L
<u>Quartz silica</u>		
Dermal	LD50	> 5,000 mg/Kg
Ingestion	LD50	> 5,000 mg/Kg
<u>Polysiloxane</u>		
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

Reproductive 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.

Reproductive and/or development effects

Polysiloxane

<u>Route</u>	<u>Target Organ/Value</u>	<u>Species</u>	<u>Test Result/Exposure Duration</u>
Ingestion	There is evidence for positive reproduction positive reproduction but limited data for classification	Rat	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

<u>Route</u>	<u>Target Organ/Value</u>	<u>Species</u>	<u>Test Result/Exposure Duration</u>
Inhalation	Silicosis - Causes damage to organs through prolonged or repeated exposure	Human	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.

Interactive effects Not available.

Where specific chemical data are not available Not available.

Mixtures Not available.

Other information No delayed and immediate effects, and chronic effects from short-term and long-term exposure are available. Some numerical measures of toxicity, including acute toxicity estimates are not available.

12: Ecological information

Do not discard material into drains/sewers or aquatic environment.

<i>Toxicity</i>	Not available.	<i>Mobility in soil</i>	Not available.
<i>Persistence and degradability</i>	Not available.	<i>Other adverse effects</i>	Not available.
<i>Bioaccumulative potential</i>	Not available.		

13: Disposal considerations

Disposal methods Not classified as hazardous waste.

14: Transport information

Not a Dangerous Good.

<i>UN Number</i>	Not applicable.	<i>UN Proper Shipping Name</i>	Not applicable.
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SAFETY DATA SHEET
maxill Vinyl Polysiloxane Impression Material

Transport hazard class(es)	Not applicable.	Environmental hazards	Not available.
Packing group	Not applicable.	Special precautions for user	Not available.

15: Regulatory information

Safety, health, and environmental regulations specific to the product in question

CANADA - This product is not subject to the Hazardous Products Act (HPA) Part II (Hazardous Products) as per paragraph 12(j); Schedule 1 (Non-Application of Part II).

This restriction states that Part II does not apply in respect of the sale or importation of anything listed in Schedule 1 which includes any pest control product as defined in subsection 2(1) of the Pest Control Products Act, any explosive as defined in Section 2 of the Explosives Act, any cosmetic, device, drug or food, as defined in Section 2 of the Food and Drugs Act, any consumer product as defined in Section 2 of the Canada Consumer Product Safety Act and any wood or product made of wood. Exempt – Medical device

USA – Medical device with restrictions: *Caution: Federal law restricts this device to sale by or on the order of a dentist/physician. Rx ONLY.*

16: Other information

Disclaimer Information contained herein was obtained from sources considered technically accurate and reliable. While every effort has been made to ensure full disclosure of product hazards, in some cases data is not available and is so stated. Since conditions of actual product use are beyond control of the supplier, it is assumed that users of this material have been fully trained according to the requirements of all applicable legislation and regulatory instruments. No warranty, expressed or implied, is made and supplier will not be liable for any losses, injuries or consequential damages which may result from the use of or reliance on any information contained in this document.

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