

Dental Health Products Inc./Health Tec

Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

Date Issued: 09/30/2015

Document Number: SDS-TCBM

Date Revised:

Revision Number: rev0

1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Temporary Crown & Bridge Material
Chemical Name/Classification:	PROVI KB (AUTOMIX 4:1)
Product Identifier (Part/Item Number):	500 Shade A1 Refill Cartridge 10 Tips, 501 Shade A2 Refill Cartridge 10 Tips, 502 Shade A3.5 Refill Cartridge 10 Tips, 502 Shade A3.5 Refill Cartridge 10 Tips, 503 Shade B1 Refill Cartridge 10 Tips
U.N. Number:	N/A
U.N. Dangerous Goods Classification:	N/A
Recommended Use:	For dental use only
Restrictions on Use:	This product should only be supplied or handled to dentists, dental technicians or upon their instructions.
Distributed by:	Dental Health Products Inc.
Distributors Address:	2614 North Sugar Bush Road,
Distributor Telephone Number:	800-626-2163 (Product Information)
Emergency Contact Telephone Number:	Chemtrec (800) 424-9300

2. HAZARD(S) IDENTIFICATION

Hazard Statements	Precautionary Statements
H313, H320	P234, P301, P305, P332, P391, P410



Dental Health Products Inc./Health Tee

Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

GHS Classification: Xi

Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008: void

Classification according to Directive 67/548/EEC or Directive 1999/45/EC: void

Information concerning particular hazards for human and environment:

The product does not have to be labeled due to the calculation procedure of the „General classification guideline for preparations of the EU“ in the latest valid version.

Label elements:

Labeling according to EU guidelines:

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 dangerous substance Directive 1999/45/EC.

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

GHS Hazard (H) and Precautionary (P) Phrases: H313, H320, P234, P301, P305, P332, P391, P410

Refer to Section 16 for the full text of the EU Classifications and H/P Phrases.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical characterization:

Description: Mixture of polyfunctional acrylates and methacrylates, unsaturated esters and malonyl urea derivatives

Hazardous components: none

Refer to Section 16 for the full text of the GHS, H and P phrases, and EU Classifications.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	rinse with plenty of water and consult a doctor
Skin	wash with plenty of water and soap
Inhalation	NA
Ingestion	If symptoms persist consult a doctor
Most important symptoms of exposure	Irritation
Other	If symptoms persist, see medical attention
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically	

Dental Health Products Inc./Health Tec





Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	CO2, water
Fire Fighting Procedures:	no special measures required
Specific Hazards Arising from the Chemical:	no special measures required
Precautions for Fire Fighters:	no special measures required

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Not Required

Environmental Precautions: Do not allow to enter drains/surface water/ ground-water

Methods and Materials for Containment and Clean-up: wipe out with absorbent material

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE



7. HANDLING AND STORAGE

Precautions for Safe Handling: For dental use only. No special measures required.

Conditions for Safe Storage: store at a dry place, storage temperature <25°C, Keep away from foodstuffs, store only in the original containers

Dental Health Products Inc./Health Tec

Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Biological Exposure Limits: NA

Appropriate Engineering Controls: NA

Individual Protection Measures (PPE)

Specific Eye/face Protection: Safety Glasses

Specific Skin Protection: Not Applicable

Specific Respiratory Protection: Not Applicable

Specific Thermal Hazards: Not Applicable

Recommended Personal Protective Equipment

EYES/FACE



Environmental Exposure Controls: NA

General Hygiene Considerations and Work Practices: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace

Protective Measures During Repair and Maintenance of Contaminated Equipment: NA

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Tooth colored paste	Explosive limits:	NA
Odor:	Nearly odorless	Vapor pressure:	Not Determined
Odor threshold:	Not Determined	Vapor density:	1,52 (20°C) g/cm3
pH:	Neutral	Relative density:	Not Determined
Melting/freezing point:	NA	Solubility:	partially soluble in toluene; insoluble in water
Initial boiling point and range:	Not Determined	Partition coefficient: n-octanol/water:	na

Dental Health Products Inc./Health Tec

Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

Flash point:	Not Determined	Auto-ignition temperature:	None
Evaporation rate:	Not Determined	Decomposition temperature:	Not Determined
Flammability:	None	Viscosity:	Paste
Explosive Properties:	Not Determined	Oxidizing Properties:	Not Determined

10. STABILITY AND REACTIVITY

Chemical stability and reactivity: Unstable, avoid heat, direct sunlight

Possibility of Hazardous Reactions: NA

Conditions to Avoid: heat, direct sunlight, peroxides, metal powders, strong oxidizers, free radical initiators

Incompatible materials: Peroxides, metal powders, strong oxidizers, free radical initiators.

Hazardous Decomposition Products: none under normal conditions of storage and use

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: repeated and prolonged exposure may cause skin irritations and eye irritation

Emergency Overview: None

Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
Eye:	Irritating	NA	NA	NA	NA	NA	NA
Skin:	NA	NA	NA	NA	NA	NA	NA
Inhalation:	NA	NA	NA	Non volatile	NA	NA	NA
Ingestion:	NA	NA	NA	Possible toxic when swallowed	NA	NA	NA
Other:	NA	NA	NA	NA	NA	NA	NA

Medical Conditions Aggravated by Exposure: Allergic reaction to methacrylate by chronic exposure to product is possible. During the long period of use as temporary crown and bridge material no health diseases are reported. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

Carcinogenicity: Not known to be carcinogenic

Dental Health Products Inc./Health Tec

Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

12. ECOLOGICAL INFORMATION

Toxicity: Not determined

Persistence and Degradability: Not determined

Bio-accumulative Potential: Not determined

Mobility in Soil: Not determined

Other Adverse Effects: Not determined

Results of PBT/vPvB Assessment: NA

General information: Avoid transfer into environment

13. DISPOSAL CONSIDERATIONS

Regulations: Small quantities can be disposed of with household waste. Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Uncleansed packaging: Recommendation: Disposal must be made according to official regulations.

Properties (Physical/Chemical) Affecting Disposal: NA

Waste Treatment Recommendations: NA

14. TRANSPORT INFORMATION

UN Identification Number: NA

UN Proper Shipping Name: NA

Transport hazard class(es): NA

Packing Group: NA

Special precautions for user: NA



Dental Health Products Inc./Health Tec

Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): N/A

Classification according to EEC-guidelines: No classification necessary to actual EEC guidelines.

Classification according to EC-guidelines: The product is a medical device according to EC-directive 93/42 EEC. The product must not be labelled according to EC-regulations or the corresponding national regulations.

Toxic Substances Control Act (TSCA): N/A

Clean Water Act (CWA): N/A

Clean Air Act (CAA): N/A

Superfund Amendments and Reauthorization Act (SARA) Title III Information: N/A

SARA Section 311/312 (40 CFR 370) Hazard Categories: N/A

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

National Prescriptions:

Classification according to VbF: N/A

Immediate Hazard:	N/A	Pressure Hazard:	N/A
Delayed Hazard:	N/A	Reactivity Hazard:	N/A
Fire Hazard:	N/A		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
N/A	N/A	N/A

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
N/A	N/A	N/A

International Regulations

Canadian Environmental Protection Act: N/A

Canadian Workplace Hazardous Materials Information System (WHMIS): N/A

European Inventory of Existing Chemicals (EINECS): N/A

Dental Health Products Inc./Health Tec

Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

H313: May be harmful in contact with skin

H320: Causes eye irritation

P234: Keep only in original container.

P301: IF SWALLOWED: If symptoms persist consult a doctor

P305: IF IN EYES: rinse with plenty of water and consult a doctor

P332: If skin irritation occurs: wash with plenty of water and soap

P391: Collect spillage.

P410: Protect from sunlight.

Xi: Irritant

Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product.

The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

Date of SDS Preparation/Revision: rev0 09/30/2015

Data Sources: Supplier