

MATERIAL SAFETY DATA SHEET

1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Name: ReTemp-LC Light Curing Temporary Filling Flowable Composite

Other Names: n/a

Recommended Use: Temporary fillings, temporary protection in inlay and onlay technique

Company name: Safe Endo Dental India Pvt. Ltd.

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2 - HAZARDS IDENTIFICATION

Health effects are based on the unmixed/uncured material.

Under FDA regulations this product is classified as a medical device.

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

Classification of the substance or mixture

Skin Sens. 1H317 May cause an allergic skin reaction.

Label elements

Hazard pictograms GHS07

Signal word Warning

Hazard statements

May cause an allergic skin reaction.

Precautionary statements

Wear protective gloves / protective clothing.

If skin irritation or rash occurs: Get medical advice/attention.

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

Other hazards Use only for intended scope of application

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 - COMPOSITION/INFORMATION ON INGREDIENTS

The Gel contains the following dangerous substances:

Chemical name	Contents (%)	w/w %	CAS	EC no.	R-Phrases
Acrylated Urethane Photoinitiators BHT,		<95			
Thickeners		<30			

4 - FIRST AID MEASURES

Description of first aid measures

After inhalation : Seek medical treatment in case of complaints.

After skin contact : Immediately wash with water and soap and rinse thoroughly.

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

After swallowing : If symptoms persist consult doctor.

Information for doctor:

Most important symptoms and effects, both acute and delayed : No further relevant information available.

Indication of any immediate medical attention and special treatment needed : No further relevant information available.

5 - FIRE-FIGHTING MEASURES

Extinguishing media

Suitable extinguishing agents:

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

Special hazards arising from the substance or mixture : No further relevant information available.

Advice for firefighters

Protective equipment : No special measures required.

6 - ACCIDENTAL RELEASE MEASURES

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

Environmental precautions : No special measures required.

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

7 - HANDLING AND STORAGE

Handling:

Precautions for safe handling : For dental use only.

Information about protection against explosions and fires : No special measures required.

Conditions for safe storage, including any incompatibilities Storage:

Requirements to be met by storerooms and receptacles : See storage instructions on package

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

Further information about storage conditions : None.

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

8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Control parameters Components 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 that were valid during the creation were used as basis.

Exposure controls

Personal protective equipment:

General protective and hygienic measures : The usual precautionary measures for handling chemicals should be followed. ·

Breathing equipment : Not required.

Protection of hands:

Protective gloves

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.

Eye protection : Not required

9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

General Information

Appearance:

Form : Pasty

Color : Blue

Odor : Characteristic

pH-value : Not determined.

Change in condition

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Flash point : Not applicable.

Auto igniting : Product is not selfigniting.

Danger of explosion : Product does not present an explosion hazard.

Density : Not determined.

Solubility in / Miscibility with Water : Not miscible or difficult to mix.

Viscosity:

Dynamic : Not determined

Kinematic : Not determined.

Other information : No further relevant information available.

10 - STABILITY AND REACTIVITY

Reactivity : No further relevant information available.

Chemical stability

Thermal decomposition / conditions to be avoided : No decomposition if used according to specifications.

Possibility of hazardous reactions : No dangerous reactions known.

Conditions to avoid : No further relevant information available.

Incompatible materials : No further relevant information available.

Hazardous decomposition products : No dangerous decomposition products known.

11 - TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity:

Primary irritant effect:

on the skin : No irritant effect

on the eye : No irritating effect

Sensitization : Sensitization possible through skin contact.

Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations

12 - *ECOLOGICAL INFORMATION*

Toxicity

Aquatic toxicity : No further relevant information available.

Persistence and degradability : No further relevant information available.

Behavior in environmental systems Bio accumulative potential : No further relevant information available.

Mobility in soil : No further relevant information available.

Additional ecological information:

General notes : Water hazard class 1 (Self-assessment): slightly hazardous for water

Results of PBT and vPvB assessment PBT : Not applicable.

vPvB : Not applicable.

Other adverse effects : No further relevant information available.

13 - *DISPOSAL CONSIDERATIONS*

Waste treatment methods Recommendation : Smaller quantities can be disposed of with household waste.

Unclean packages Recommendation : Disposal must be made according to official regulations

14 *TRANSPORT INFORMATION*

UN-Number

DOT, ADR, ADN, IMDG, IATA : Void

UN proper shipping name

DOT, ADR, ADN, IMDG, IATA : Void

Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA Class : Void

Packing group

DOT, ADR, IMDG, IATA : Void

Environmental hazards:

Marine pollutant : No

Special precautions for user : Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code : Not applicable o Void

15 - *REGULATORY INFORMATION*

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

Section 355 (extremely hazardous substances) : None of the ingredients are listed.

Section 313 (Specific toxic chemical listings) : None of the ingredients are listed.

TSCA (Toxic Substances Control Act):

One or more substances contained in this material are not listed on the TSCA Inventory. Contact VOCO for more information.

Proposition 65

Chemicals known to cause cancer:

None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for females: None of the ingredients are listed

Chemicals known to cause reproductive toxicity for males: None of the ingredients are listed

Chemicals known to cause developmental toxicity: None of the ingredients are listed

Carcinogenicity categories

EPA (Environmental Protection Agency) None of the ingredients are listed

TLV (Threshold Limit Value established by ACGIH) Contact VOCO for more information.

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients are listed

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms GHS07

Signal word Warning

Hazard statements

May cause an allergic skin reaction.

Precautionary statements Wear protective gloves / protective clothing. If skin irritation or rash occurs : Get medical advice/attention. Dispose of contents/container in accordance with local/regional/national/international regulations.

16 - OTHER INFORMATION

The above information applies to customer packages unless stated otherwise, and fully expresses our current knowledge and experience. The product is assumed for use at worksites corresponding to its designation, and the instructions on the enclosed instruction sheet as well as the standard labor safety regulations for the handling of chemical products are assumed to be adhered to.