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## 1. Identification of the substance/mixture and of the Company/undertaking:

1.1 Product identifier:

Product Name: Shade Modification Kit

1.2 Relevant identified use:

Relevant use:

Dental professional use: For the masking of tooth colour defects.

1.3 Details of the supplier of the Safety Data Sheet:

# **Manufacturer / Supplier**

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# 2. Hazard Identification

Classification of the substance/mixture:

SIGNAL WORD: WARNING:



GHS Classification: Skin Sens. 1

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#### 2. Hazard Identification

Hazard statements:

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing vapour.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves. P102 Keep out of reach of children.

P103 Read instructions for use before use.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water P333+P313 If skin irritation occurs,: Get medical advice/attention. Specific treatment- see product Instructions for Use.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant

Other: Product may cause irritation to the skin, eye and mucous membrane. Ingestion of

unpolymerised material may cause gastric irritation. In isolated cases, contact allergies have been reported with acrylic resins. Anyone with known history of resin allergies are

advised to seek the advice of a specialist before use.

3. Composition / Information on ingredients

<u>Composition</u>: <u>CAS No.</u> <u>Wt. %</u>

Acrylic monomer - 65.0 Balance ingredient (non-hazardous) 35.0

Hazard classification:

Skin Sens. 1: H317.

#### 4. First Aid Measures

Eye (contact): Flush opened eye with running water for at least 5 minutes. Seek medical

attention.

Skin (contact): Remove contaminated clothing. Wash skin with soap and water. In case of

allergic reaction, seek medical attention.

Ingestion: Seek medical attention.

Inhalation None expected. If feeling unwell, Remove victim to fresh air and keep at rest in a

position comfortable for breathing. Call a POISON CENTRE or doctor/physician if

you well.

Most important effects, acute and delayed:

The most important known symptoms and effects are described in section 2

and/or in section 11.

Indication of any immediate medical attention and special treatment needed: No data available.

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## 5. Fire Fighting Measures

Suitable extinguishing media: Dry powder, vaporising liquid or foam extinguisher.

Unusual Fire and Explosion Hazards: Heat can cause polymerization with rapid release of energy

which may melt the container.

Unsuitable extinguishing media: No data available.

Specific hazards arising

from the mixture: Combustible.

Slight fire hazard when exposed to heat or flame.

Special protective equipment: No special measures required for small quantity (less than 1

kg). For large quantity, wear approved respirator and

protective gear. Use water spray to cool container.

Advice for firefighters: Wear self contained breathing apparatus for fire fighting if

necessary.

#### 6. Accidental Release Measures

For non-emergency personnel:

Personal precautions: Not required.

Environmental precautions: Prevent any spillage from entering waterways, drains or sewage

system.

Methods for cleaning up

Handling and storage

7.

and containment: Mop up spillage with absorbance paper/cloth soaked in

ethanol/acetone. Dispose of in accordance with local regulations.

Removal of ignition sources: Eliminate sources of ignition.

<u>Precautions for safe handling:</u> Replace caps immediately after use.

Conditions for safe storage, including any biocompatibilities:

Store in a cool place at temperatures between 10°C and 25°C

 $(50^{\circ} - 77^{\circ}F)$ . Keep out of direct light.

Specific end use: Apart from the use mentioned in section 1.2, there are no other

uses for the product.

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## 8. Exposure controls and personal protection

Control parameters:

Occupational Exposure Limits: We are not aware of any national exposure limit.

Exposure controls:

Respiratory protection: None required under normal conditions of use.

Hand protection: Rubber, latex or PVC gloves.

Eye protection: Safety glasses, goggles or face shield.

General safety and hygiene measures: Follow good housekeeping practices and good industrial hygiene in

handling this material. Remove any naked lights or strong

heat sources.

## 9. Physical and chemical properties

Appearance: Coloured semi-translucent / opaque viscous liquid.

Odour: Ester like.

Boiling point: Gel before boiling.

Melting point: Not established.

Specific gravity: 1.1 - 1.2

Flash point: Not established. Flammable: Not established.

Autoflammability: Do not self-ignite at ambient temperature.

Explosive properties: Do not present an explosion hazard.

Oxidizing properties:

Vapour pressure (@ 20°C):

Relative density:

Solubility:

Auto-ignition temperature:

Not established.

Not established.

Not established.

Not established.

Not established

becomposition temperature. Not established

Initial boiling point and boiling range: Not established

pH: Not established

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### 10. Stability and Reactivity

Reactivity: No data available.

Chemical Stability: Stable under normal conditions.

Conditions to avoid: Avoid heat, ignition sources, aging, contamination and intense

visible light.

Materials to avoid: Free radical formers, e.g. peroxides, reducing substances and /

Reacts violently with bromoform and or heavy metals ions. chloroform in the presence of alkalis or in contact with alkaline surfaces. Decomposes violently in contact with nitric / sulfuric

acid mixtures.

Hazardous decomposition products: None under normal conditions; oxides of carbon when burned.

Hazardous reactivity (polymerization): and intense light can cause polymerization.

Spontaneous polymerization may occur in the presence of

radical formers.

May polymerize under these conditions with heat evolution.

May ignite in the presence of sparks or naked flame.

## 11. Toxicological information

Acute toxicity: May be skin sensitising.

Urethane dimethacrylate CAS 72869-86-4: Oral (rat) LD50 > 2000mg/kg Triethylene glycol dimethacrylate CAS 109-16-0: Oral (rat) LD50 10837mg/kg:

Oral (mouse): LD50 10750 mg/kg.

Nil irritation reported.

Serious eye damage/irritation: Possible irritant. Skin corrosion/irritation: Possible irritant.

Respiratory or skin sensitisation: No effects expected if inhaled.

May cause allergy/sensitisation on skin contact.

Ingestion: Slightly toxic. May cause gastric irritation.

Germ cell mutagenicity: No data available.

Carcinogenicity: IARC: No component of this product present at levels greater

> equal to 0.1% is identified as probable, possible than or

human carcinogen by IARC. or confirmed

(IARC: International Agency for Research on Cancer, by the

World Health Organisation (WHO)).

No data available. Reproductive toxicity:

Specific target organ toxicity – single exposure: May cause irritation to eyes, skin and inhalation.

Specific target organ toxicity – repeated exposure: No data available. No data available. Aspiration hazard:

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Self assessment: Slightly hazardous for water. Do not allow large quantities to

reach sewage system and waterways.

Ecotoxicity: No data available.

Persistence and biodegradeability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and VPvB assessment: PBT/VPvB assessment not available as chemical safety

assessment not required/not conducted.

Other adverse effects: No data available.

## 13. Disposal considerations

Dispose of in accordance with local official regulations.

Contaminated packaging:

Dispose of contaminated packaging as hazardous waste in accordance with local official regulations.

#### 14. Transport information

This product is not considered to be a dangerous good within the meaning of transportation regulations.

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# 15. Regulatory information

These products are regulated by: TGA

Medical Devices Directive 93/42/EEC

FDA

National regulations

#### 16. Other information

The information provided herein is given in good faith, but no warranty expressed or implied is made.

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**Department issuing SDS:** Research and Development

**Contact:** R&D Director