SAFETY DATA SHEETS

This SDS packet was issued with item:

074389078

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

074389110 074310538 074389003 074389011 074389029 074389037 074389045 074389052 074389060 074389086 074389094 074389102

Material Safety Data Sheet

in accordance with Community Regulation 2006/1907/EC (R.E.A.C.H.)

Revision Date: 05th September 2008

SECTION 1

Product & Company identification

1.1 Product name

PREMISE FLOWABLE (all shades)

1.2 <u>Uses/Application</u>:

Dental restorative material.

1.3 Company (Name, address and info phone number)

KERR ITALIA S.r.l.

Via Passanti, 332

84018 Scafati (SA) - Italy

Free Phone: 00-800-41-050-505

1.4 Emergency phone (according to communitarian directive 99/45/EC, article 17)

+39.081.8508.325 (08.00-17.00, European time, GMT+1)

E-mail address: safety@kerrhawe.com

SECTION 2

Hazard identification

2.1 <u>Hazard classification</u> (according to communitarian directives 67/548/EEC & 99/45/EC) Sensitizing.

2.2 Other hazard

Uncured material may be harmful if swallowed.

SECTION 3

Composition/Information on Ingredients

(according to communitarian directives 67/548/EEC, 99/45/EC & 2001/58/EC)

3.1 <u>Hazardous ingredients</u>

| HAZARDOUS | % | HAZARD | RISK | CAS N. | EINECS |
|------------------------|-------|----------------|----------|---------------|-----------|
| INGREDIENTS | | SYMBOLS | PHRASES | | N. |
| Benzoyl Peroxide (BPO) | < 1 | E; Xi | 2-36-43 | 94-36-0 | 202-327-6 |
| Mixture of: | | | | | |
| Propylene Carbonate | < 0,5 | Xi | 36 | 108-32-7 | 203-572-1 |
| and Antimonate salts | < 0,5 | Xi; N | 43-50/53 | (71449-78-0 & | 403-500-0 |
| | | | | 89452-37-9) | |
| Dibutyl Phtalate (DBP) | < 0,5 | T; N | 61-62-50 | 84-74-2 | 201-557-4 |

3.2 Other non-hazardous ingredients

Uncured Methacrylate Ester Monomers, Titanium Dioxide (TiO₂) and pigments.

SECTION 4

First aid measures

- <u>4.1 Treatment for eye contact</u>: Flush with water for 15 minutes including under eyelids. If irritation persists, seek medical attention.
- 4.2 Treatment for skin contact: Wash thoroughly with soap and water.
- 4.3 Treatment for inhalation (breathing): Remove to fresh air. If irritation persists, seek medical attention.
- <u>4.4 Treatment for ingestion (swallowing)</u>: Rinse mouth out with water do not induce vomiting. Seek medical attention.

SECTION 5

Fire-fighting Measures

- 5.1 Suitable extinguishing media: Chemical foam, CO₂, dry chemical.
- 5.2 Forbidden extinguishing media: Unknown.
- <u>5.3 Special fire fighting measures</u>: None. Wear a self contained breathing apparatus.
- 5.4 Unusual fire and explosion hazards: Heat can cause polymerization with rapid release of energy.
- 5.5 Special protection equipment: Sealed overall against liquids and gases.

SECTION 6

Accidental Release Measures

- 6.1 Personal Precautions: Follow recommended precautions listed in other sections.
- <u>6.2 Environmental Precautions:</u> Material should not be allowed to drain into sewers.
- <u>6.3 Reclaiming Methods:</u> Absorb spills with inert material. Prevent spilled material to reach sewers.

SECTION 7

Handling and Storage (according to article 5 of communitarian directive 98/24/EC)

- 7.1 Handling Precautions: Handle away from sources of ignition. Avoid exposure to excessive heat.
- 7.2 Precautions in case of Fire and Explosion: Extinguish all ignition sources.
- 7.3 Storage Conditions: Store in a cool, dry place away from heat, light and ignition sources.
- 7.4 Suggested container(s): Original sealed containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid the contact with reducing and oxidizing agents, peroxides and amines.
- 7.6 Environmental precautions: Do not allow product to reach sewers and rivers.
- 7.7 Other Precautions: Use according to directions.

| SECTION 8 | | |
|--|--|--|
| Exposure controls/personal protection | | |
| 8.1 Exposure Limits: | <u>PEL/TLV</u> (TiO ₂): 3,1ppm (10mg/m ³); (BPO): 0,5ppm (5 mg/m ³); | |
| 1 | (DBP): 0,4 ppm (5 mg/m ³) | |
| 8.2 Exposure control measures | <u>x</u> | |
| 8.2.1 Precautionary Meas | | |
| (according to communita | urian directives 89/686/EEC & article 4 of 98/24/EC) | |
| | Local Exhaust Ventilation: Good general ventilation should be sufficient to | |
| | control airborne levels of vapours released by | |
| Ventilation: | uncured material. | |
| | Special Ventilation: None required. | |
| | Mechanical (General) Ventilation: Good general ventilation recommended. | |
| | Other Ventilation: None required. | |
| Respiratory Protection: | Avoid prolonged or excessive breathing of vapours of uncured material | |
| Hands Protection: | Impervious rubber gloves recommended when contacting uncured material | |
| Eyes Protection: | Not required if used as directed. Safety glasses may be used. | |
| Skin Protection: | Handle in accordance with good personal hygiene and safety practices. | |
| | These practices include avoiding unnecessary exposure to uncured material. | |
| Other Protective Equipments: | It would be better to use a lab coat. | |
| Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC) | | |
| 8.2.2 Environment exposure control measures | | |
| Not Applicable. | | |

| SECTION 9 | | |
|---|--|--|
| Physical and Chemical Properties | | |
| 9.1 General information | | |
| Appearance: Pigmented paste | Odour: Fruity ester-like odour. | |
| 9.2 Information related to health, safety and envir | conment | |
| <u>pH</u> : Not available | Relative density: Not determined | |
| Boiling point: Not determined (N/D) | Specific gravity: 2,5 g/ml | |
| Flash point: Not determined | Solubility: Insoluble | |
| <u>Flammability</u> : Not flammable. | Partition coefficient n-octanol/water: N/D | |
| Lower Explosivity Limit (L.E.L.): N/A | <u>Viscosity</u> : Not determined | |
| <u>Upper Explosivity Limit (U.E.L.)</u> : N/A | <u>Vapour density (air = 1)</u> : Not determined | |
| Oxidizing properties: None | Evaporation rate (n-butane = 1): Not determined | |
| <u>Vapour pressure</u> : Not determined | Melting point: Not determined | |
| 9.3 Other information (according to communitarian directive 94/9/EC): | | |
| Miscibility: Not determined | Conducibility: Not determined | |
| Solubility in Lipids: Not determined | Gases Group: N/A | |

SECTION 10

Stability and Reactivity

Stability: Stable if stored as directed.

10.1 Conditions to avoid: Heat, light, aging and contamination.

10.2 Materials to avoid (incompatibility): Reducing and oxidizing agents, peroxides and amines.

10.3 Hazardous decomposition products: Carbon oxides.

Other precautions:

Hazardous Polymerization Products: May occur

Safety significance in case of change in physical appearance: None

<u>Stabilizers</u>: The product is stabilized with non-hazardous polymerization inhibitors.

SECTION 11

Toxicological Information

CMR effects (Carcinogenicity, Mutagenicity and toxicity for reproduction):

No

Effects and hazards of eye contact: May cause irritation and damage if not removed promptly.

Effects and hazards of skin contact: Prolonged or repeated exposure to uncured material may cause irritation or skin rash especially in sensitive individuals.

<u>Effects and hazards of Inhalation (Breathing)</u>: Prolonged or excessive inhalation may cause respiratory tract irritation.

Effects and hazards of Ingestion (Swallowing): Uncured material may be harmful if swallowed.

Effects for prolonged Exposure: Unknown.

<u>Toxic-kinetic effects</u>: Unknown. Effects on metabolism: Unknown.

Toxicological data for ingredients:

| Titanium Dioxide | LD ₅₀ (oral rat) | > 20000 mg/Kg |
|------------------|--|---------------|
| | LD ₅₀ (skin rabbit) | > 10000 mg/Kg |
| | LC ₅₀ (inhalation rat/4hrs) | > 6,8 mg/l |
| BPO | LD ₅₀ (oral rat) | > 5000 mg/Kg |
| | LC ₅₀ (inhalation rat/4hrs) | > 24,3 mg/l |
| DBP | LD ₅₀ (oral rat) | 8000 mg/Kg |
| | LD ₅₀ (skin rabbit) | 20000 mg/Kg |

SECTION 12

Ecological Information

This product has not known ecological hazardous effects.

12.1 Eco-toxicity: Not available

12.2 Mobility: Not available

12.3 Persistence and degradability: Not available

12.4 Bioaccumulative potential: Not available

12.5 Results of PBT (Persistent Bio-Toxicity) assessment: Not available

12.6 Other adverse effects: Not available

Aquatic toxicity data for ingredients:

| Titanium Dioxide | LC ₅₀ (Leuciscus Idus) | > 1000 mg/l (48 hours) |
|------------------|--|-------------------------|
| | EC ₅₀ (Daphnia magna, crustacea) | > 3 mg/l (30days) |
| | EC ₅₀ (Pseudomonas fluorescens) | > 10000 mg/l (24 hours) |
| BPO | LC ₅₀ (Fishes, acute toxicity) | 2,0 mg/l (96 hours) |
| | EC ₅₀ (Daphnia) | 2,91 mg/l (48 hours) |
| | EC ₅₀ (Bacteria, breathing inhibition of active muds) | 35 mg/l |
| DBP | LC ₅₀ (Fishes, acute toxicity) | 1,2 mg/l (96 hours) |
| | LC ₅₀ (Daphnia) | 1-10 mg/l (96 hours) |
| | • / | , , , |

SECTION 13

Disposal considerations

Unpolymerized (uncured) material may be hazardous waste. Dispose of in accordance of local regulations.

SECTION 14

Transport information

14.1 Sea transportation (IMDG)

The product is not regulated.

14.2 Air transportation (ICAO/IATA)

The product is not regulated.

14.3 Transportation by Road/Railway (RID/ADR)

The product is not regulated.

SECTION 15 (Classification according to communitarian directives 67/548/EEC & 99/45/EC)

Regulatory information

Hazard labelling not required.

This product is an exempted medical device (directive 1999/45/EC, article 1, paragraph 5g).

SECTION 16

Other information

16.1 Risk phrases of all ingredients

- 43 May cause sensitisation by skin contact.
- 2 Risk of explosion by shock, friction, fire or other source of ignition
- 36 Irritating to eyes.
- 50/53 Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.
- May cause harm to the unborn child
- 62 Possible risk of impaired fertility

16.1.1 Safety phrases of all ingredients

- 2 Keep out of the reach of children.
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- Avoid release to the environment. Refer to special instructions / safety data sheets

16.2 Sources of key data used to compile the Safety Data Sheet:

European Chemicals Bureau (ECB – www.ecb.jrc.it)

European chemical Substances Information System (ESIS - www.ecb.jrc.it/esis)

A.C.G.I.H. (www.acgih.org)

N.I.OS.H. (www.cdc.gov/niosh/)

O.S.H.A. (www.osha.gov/)

U.E. (www.europa.eu/index it.htm)

I.A.R.C. (www.iarc.fr/)

N.T.P. (www.**ntp**.niehs.nih.gov)

European Community Directives:

| Classification, packaging and labelling of dangerous substances. |
|---|
| Directive concerning the approximation of the laws, regulations and administrative |
| provisions of the Member States relating to the classification, packaging and labelling of |
| dangerous preparations. |
| Second amendment of directive 91/155/EEC for the definition of a detailed arrangement |
| of specific information relating to dangerous preparations (art. 14 of 99/45/EC) and |
| substances (art. 27 of 67/548/EEC). |
| Directive on the minimum health and safety requirements for the use by workers of |
| personal protective equipment at the workplace (third individual directive within the |
| meaning of Article 16 (1) of Directive 89/391/EEC). |
| Approximation of the laws of the Member States relating to personal protective |
| equipment. |
| Approximation of the laws of the Member States concerning equipment and protective |
| systems intended for use in potentially explosive atmospheres |
| Protection of the health and safety of workers from the risks related to chemical agents at |
| work. |
| |

<u>Document modification history</u>: First version in compliance of Community Regulation 2006/1907/EC (R.E.A.Ch.)

CAUTION: PRODUCT FOR PROFESSIONAL USE

The information on this Safety Sheet is based on presently available data and to our best knowledge for the correct handling of the product under normal conditions. Any use of this product in any way not indicated on this Sheet or the use of this product together with any other process/procedure will be exclusively under the user's responsibility. This document does not constitute explicit or implicit warranty of product quality or fitness for a particular purpose.

Material Safety Data Sheet

in accordance with Community Regulation 2006/1907/EC (R.E.A.C.H.)

Revision Date: 05th September 2008

SECTION 1

Product & Company identification

1.1 Product name

PREMISE FLOWABLE (all shades)

1.2 <u>Uses/Application</u>:

Dental restorative material.

1.3 Company (Name, address and info phone number)

KERR ITALIA S.r.l.

Via Passanti, 332

84018 Scafati (SA) - Italy

Free Phone: 00-800-41-050-505

1.4 Emergency phone (according to communitarian directive 99/45/EC, article 17)

+39.081.8508.325 (08.00-17.00, European time, GMT+1)

E-mail address: safety@kerrhawe.com

SECTION 2

Hazard identification

2.1 <u>Hazard classification</u> (according to communitarian directives 67/548/EEC & 99/45/EC) Sensitizing.

2.2 Other hazard

Uncured material may be harmful if swallowed.

SECTION 3

Composition/Information on Ingredients

(according to communitarian directives 67/548/EEC, 99/45/EC & 2001/58/EC)

3.1 <u>Hazardous ingredients</u>

| HAZARDOUS | % | HAZARD | RISK | CAS N. | EINECS |
|------------------------|-------|----------------|----------|---------------|-----------|
| INGREDIENTS | | SYMBOLS | PHRASES | | N. |
| Benzoyl Peroxide (BPO) | < 1 | E; Xi | 2-36-43 | 94-36-0 | 202-327-6 |
| Mixture of: | | | | | |
| Propylene Carbonate | < 0,5 | Xi | 36 | 108-32-7 | 203-572-1 |
| and Antimonate salts | < 0,5 | Xi; N | 43-50/53 | (71449-78-0 & | 403-500-0 |
| | | | | 89452-37-9) | |
| Dibutyl Phtalate (DBP) | < 0,5 | T; N | 61-62-50 | 84-74-2 | 201-557-4 |

3.2 Other non-hazardous ingredients

Uncured Methacrylate Ester Monomers, Titanium Dioxide (TiO₂) and pigments.

SECTION 4

First aid measures

- <u>4.1 Treatment for eye contact</u>: Flush with water for 15 minutes including under eyelids. If irritation persists, seek medical attention.
- 4.2 Treatment for skin contact: Wash thoroughly with soap and water.
- 4.3 Treatment for inhalation (breathing): Remove to fresh air. If irritation persists, seek medical attention.
- <u>4.4 Treatment for ingestion (swallowing)</u>: Rinse mouth out with water do not induce vomiting. Seek medical attention.

SECTION 5

Fire-fighting Measures

- 5.1 Suitable extinguishing media: Chemical foam, CO₂, dry chemical.
- 5.2 Forbidden extinguishing media: Unknown.
- <u>5.3 Special fire fighting measures</u>: None. Wear a self contained breathing apparatus.
- 5.4 Unusual fire and explosion hazards: Heat can cause polymerization with rapid release of energy.
- 5.5 Special protection equipment: Sealed overall against liquids and gases.

SECTION 6

Accidental Release Measures

- 6.1 Personal Precautions: Follow recommended precautions listed in other sections.
- <u>6.2 Environmental Precautions:</u> Material should not be allowed to drain into sewers.
- <u>6.3 Reclaiming Methods:</u> Absorb spills with inert material. Prevent spilled material to reach sewers.

SECTION 7

Handling and Storage (according to article 5 of communitarian directive 98/24/EC)

- 7.1 Handling Precautions: Handle away from sources of ignition. Avoid exposure to excessive heat.
- 7.2 Precautions in case of Fire and Explosion: Extinguish all ignition sources.
- 7.3 Storage Conditions: Store in a cool, dry place away from heat, light and ignition sources.
- 7.4 Suggested container(s): Original sealed containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid the contact with reducing and oxidizing agents, peroxides and amines.
- 7.6 Environmental precautions: Do not allow product to reach sewers and rivers.
- 7.7 Other Precautions: Use according to directions.

| SECTION 8 | | |
|--|--|--|
| Exposure controls/personal protection | | |
| 8.1 Exposure Limits: | <u>PEL/TLV</u> (TiO ₂): 3,1ppm (10mg/m ³); (BPO): 0,5ppm (5 mg/m ³); | |
| 1 | (DBP): 0,4 ppm (5 mg/m ³) | |
| 8.2 Exposure control measures | <u>x</u> | |
| 8.2.1 Precautionary Meas | | |
| (according to communita | urian directives 89/686/EEC & article 4 of 98/24/EC) | |
| | Local Exhaust Ventilation: Good general ventilation should be sufficient to | |
| | control airborne levels of vapours released by | |
| Ventilation: | uncured material. | |
| | Special Ventilation: None required. | |
| | Mechanical (General) Ventilation: Good general ventilation recommended. | |
| | Other Ventilation: None required. | |
| Respiratory Protection: | Avoid prolonged or excessive breathing of vapours of uncured material | |
| Hands Protection: | Impervious rubber gloves recommended when contacting uncured material | |
| Eyes Protection: | Not required if used as directed. Safety glasses may be used. | |
| Skin Protection: | Handle in accordance with good personal hygiene and safety practices. | |
| | These practices include avoiding unnecessary exposure to uncured material. | |
| Other Protective Equipments: | It would be better to use a lab coat. | |
| Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC) | | |
| 8.2.2 Environment exposure control measures | | |
| Not Applicable. | | |

| SECTION 9 | | |
|---|--|--|
| Physical and Chemical Properties | | |
| 9.1 General information | | |
| Appearance: Pigmented paste | Odour: Fruity ester-like odour. | |
| 9.2 Information related to health, safety and envir | conment | |
| <u>pH</u> : Not available | Relative density: Not determined | |
| Boiling point: Not determined (N/D) | Specific gravity: 2,5 g/ml | |
| Flash point: Not determined | Solubility: Insoluble | |
| <u>Flammability</u> : Not flammable. | Partition coefficient n-octanol/water: N/D | |
| Lower Explosivity Limit (L.E.L.): N/A | <u>Viscosity</u> : Not determined | |
| <u>Upper Explosivity Limit (U.E.L.)</u> : N/A | <u>Vapour density (air = 1)</u> : Not determined | |
| Oxidizing properties: None | Evaporation rate (n-butane = 1): Not determined | |
| <u>Vapour pressure</u> : Not determined | Melting point: Not determined | |
| 9.3 Other information (according to communitarian directive 94/9/EC): | | |
| Miscibility: Not determined | Conducibility: Not determined | |
| Solubility in Lipids: Not determined | Gases Group: N/A | |

SECTION 10

Stability and Reactivity

Stability: Stable if stored as directed.

10.1 Conditions to avoid: Heat, light, aging and contamination.

10.2 Materials to avoid (incompatibility): Reducing and oxidizing agents, peroxides and amines.

10.3 Hazardous decomposition products: Carbon oxides.

Other precautions:

Hazardous Polymerization Products: May occur

Safety significance in case of change in physical appearance: None

<u>Stabilizers</u>: The product is stabilized with non-hazardous polymerization inhibitors.

SECTION 11

Toxicological Information

CMR effects (Carcinogenicity, Mutagenicity and toxicity for reproduction):

No

Effects and hazards of eye contact: May cause irritation and damage if not removed promptly.

Effects and hazards of skin contact: Prolonged or repeated exposure to uncured material may cause irritation or skin rash especially in sensitive individuals.

<u>Effects and hazards of Inhalation (Breathing)</u>: Prolonged or excessive inhalation may cause respiratory tract irritation.

Effects and hazards of Ingestion (Swallowing): Uncured material may be harmful if swallowed.

Effects for prolonged Exposure: Unknown.

<u>Toxic-kinetic effects</u>: Unknown. Effects on metabolism: Unknown.

Toxicological data for ingredients:

| Titanium Dioxide | LD ₅₀ (oral rat) | > 20000 mg/Kg |
|------------------|--|---------------|
| | LD ₅₀ (skin rabbit) | > 10000 mg/Kg |
| | LC ₅₀ (inhalation rat/4hrs) | > 6,8 mg/l |
| BPO | LD ₅₀ (oral rat) | > 5000 mg/Kg |
| | LC ₅₀ (inhalation rat/4hrs) | > 24,3 mg/l |
| DBP | LD ₅₀ (oral rat) | 8000 mg/Kg |
| | LD ₅₀ (skin rabbit) | 20000 mg/Kg |

SECTION 12

Ecological Information

This product has not known ecological hazardous effects.

12.1 Eco-toxicity: Not available

12.2 Mobility: Not available

12.3 Persistence and degradability: Not available

12.4 Bioaccumulative potential: Not available

12.5 Results of PBT (Persistent Bio-Toxicity) assessment: Not available

12.6 Other adverse effects: Not available

Aquatic toxicity data for ingredients:

| Titanium Dioxide | LC ₅₀ (Leuciscus Idus) | > 1000 mg/l (48 hours) |
|------------------|--|-------------------------|
| | EC ₅₀ (Daphnia magna, crustacea) | > 3 mg/l (30days) |
| | EC ₅₀ (Pseudomonas fluorescens) | > 10000 mg/l (24 hours) |
| BPO | LC ₅₀ (Fishes, acute toxicity) | 2,0 mg/l (96 hours) |
| | EC ₅₀ (Daphnia) | 2,91 mg/l (48 hours) |
| | EC ₅₀ (Bacteria, breathing inhibition of active muds) | 35 mg/l |
| DBP | LC ₅₀ (Fishes, acute toxicity) | 1,2 mg/l (96 hours) |
| | LC ₅₀ (Daphnia) | 1-10 mg/l (96 hours) |
| | • / | , , , |

SECTION 13

Disposal considerations

Unpolymerized (uncured) material may be hazardous waste. Dispose of in accordance of local regulations.

SECTION 14

Transport information

14.1 Sea transportation (IMDG)

The product is not regulated.

14.2 Air transportation (ICAO/IATA)

The product is not regulated.

14.3 Transportation by Road/Railway (RID/ADR)

The product is not regulated.

SECTION 15 (Classification according to communitarian directives 67/548/EEC & 99/45/EC)

Regulatory information

Hazard labelling not required.

This product is an exempted medical device (directive 1999/45/EC, article 1, paragraph 5g).

SECTION 16

Other information

16.1 Risk phrases of all ingredients

- 43 May cause sensitisation by skin contact.
- 2 Risk of explosion by shock, friction, fire or other source of ignition
- 36 Irritating to eyes.
- 50/53 Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.
- May cause harm to the unborn child
- 62 Possible risk of impaired fertility

16.1.1 Safety phrases of all ingredients

- 2 Keep out of the reach of children.
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- Avoid release to the environment. Refer to special instructions / safety data sheets

16.2 Sources of key data used to compile the Safety Data Sheet:

European Chemicals Bureau (ECB – www.ecb.jrc.it)

European chemical Substances Information System (ESIS - www.ecb.jrc.it/esis)

A.C.G.I.H. (www.acgih.org)

N.I.OS.H. (www.cdc.gov/niosh/)

O.S.H.A. (www.osha.gov/)

U.E. (www.europa.eu/index it.htm)

I.A.R.C. (www.iarc.fr/)

N.T.P. (www.**ntp**.niehs.nih.gov)

European Community Directives:

| Classification, packaging and labelling of dangerous substances. |
|---|
| Directive concerning the approximation of the laws, regulations and administrative |
| provisions of the Member States relating to the classification, packaging and labelling of |
| dangerous preparations. |
| Second amendment of directive 91/155/EEC for the definition of a detailed arrangement |
| of specific information relating to dangerous preparations (art. 14 of 99/45/EC) and |
| substances (art. 27 of 67/548/EEC). |
| Directive on the minimum health and safety requirements for the use by workers of |
| personal protective equipment at the workplace (third individual directive within the |
| meaning of Article 16 (1) of Directive 89/391/EEC). |
| Approximation of the laws of the Member States relating to personal protective |
| equipment. |
| Approximation of the laws of the Member States concerning equipment and protective |
| systems intended for use in potentially explosive atmospheres |
| Protection of the health and safety of workers from the risks related to chemical agents at |
| work. |
| |

<u>Document modification history</u>: First version in compliance of Community Regulation 2006/1907/EC (R.E.A.Ch.)

CAUTION: PRODUCT FOR PROFESSIONAL USE

The information on this Safety Sheet is based on presently available data and to our best knowledge for the correct handling of the product under normal conditions. Any use of this product in any way not indicated on this Sheet or the use of this product together with any other process/procedure will be exclusively under the user's responsibility. This document does not constitute explicit or implicit warranty of product quality or fitness for a particular purpose.



SAFETY DATA SHEET

Premise Flowable

Section 1. Identification

GHS product identifier

: Premise Flowable

Other means of identification

: Not available.

Product type

: Paste.

Relevant identified uses of the substance or mixture and uses advised against

Product use : Dental product: Composite Area of application : Professional applications.

Manufacturer : Kerr Corporation

> 1717 West Collins Avenue Orange, CA 92867-5422

Telephone no.: 1-800-KERR-123

e-mail address of person responsible for this SDS

: edwin.varela@kavokerrgroup.com

Emergency telephone number (with hours of

operation)

: CHEMTREC® (24 hours) U.S. : 1-800-424-9300 International: +1-703-527-3887

Section 2. Hazards identification

OSHA/HCS status

: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Health effects are based on the uncured material.

Classification of the substance or mixture

: SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract

irritation) - Category 3

Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 28.5%

GHS label elements

Hazard pictograms



Signal word

: Warning

Hazard statements

: Causes serious eye irritation. Causes skin irritation.

May cause respiratory irritation.

Precautionary statements

Date of issue/Date of revision : 04/06/2015 Date of previous issue

: No previous validation

Version :1

1/12

Section 2. Hazards identification

Prevention : Wear protective gloves. Wear eye or face protection. Use only outdoors or in a well-

ventilated area. Avoid breathing vapor. Wash hands thoroughly after handling.

Response : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or physician if you feel unwell. IF ON SKIN: Wash

with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical attention. 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 attention.

Storage : Store locked up.

Disposal : Dispose of contents and container in accordance with all local, regional, national and

international regulations.

Hazards not otherwise

: None known.

classified

Section 3. Composition/information on ingredients

Substance/mixture : Mixture Other means of : Not available.

identification

CAS number/other identifiers

CAS number : Not applicable. **Product code** : Not available.

| Ingredient name | Other names | % | CAS number |
|---|--|-------|------------|
| Poly(oxy-1,2-ethanediyl), α ,α'-[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]- | Not available. | 10-30 | 41637-38-1 |
| 3-trimethoxysilylpropyl methacrylate | 3-trimethoxysilylpropyl methacrylate | 5-10 | 2530-85-0 |
| 2,2'-ethylenedioxydiethyl dimethacrylate | 2,2'-ethylenedioxydiethyl dimethacrylate | 5-10 | 109-16-0 |
| 2-ethylhexyl 4-(dimethylamino)benzoate | 2-ethylhexyl 4- (dimethylamino)benzoate | 1-5 | 21245-02-3 |

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health and hence require reporting in this section.

Section 4. First aid measures

Description of necessary first aid measures

: No special measures are required. In case of contact with eyes, rinse immediately with **Eve contact**

plenty of water. Get medical attention if symptoms occur.

: No special measures required. If inhaled, remove to fresh air. Get medical attention if Inhalation

symptoms occur.

Skin contact : No special measures required. In case of contact, immediately flush skin with plenty of

water. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. If material has been swallowed and the exposed person is

conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or

are severe.

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Section 4. First aid measures

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : Causes serious eye irritation. Inhalation : May cause respiratory irritation.

Skin contact : Causes skin irritation.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

: Adverse symptoms may include the following: Eve contact

> pain or irritation watering

redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

Skin contact : Adverse symptoms may include the following:

> irritation redness

Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

: In case of inhalation of decomposition products in a fire, symptoms may be delayed. Notes to physician

The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : In case of major fire and large quantities: No action shall be taken involving any

personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing

media

: Do not use water jet.

Specific hazards arising from the chemical

Hazardous thermal

decomposition products

: In a fire or if heated, a pressure increase will occur and the container may burst.

: Decomposition products may include the following materials:

carbon dioxide carbon monoxide nitrogen oxides

halogenated compounds metal oxide/oxides

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Section 5. Fire-fighting measures

Special protective actions for fire-fighters

: In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely

For emergency responders

: Low release. See also the information in "For non-emergency personnel".

Environmental precautions

: Low release. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill

: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Large spill

: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Section 7. Handling and storage

Precautions for safe handling

Protective measures

: No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose in a safe manner.

Advice on general occupational hygiene

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities

: Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls

: No special measures are required for small quantities under normal and intended conditions of product use.

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Section 8. Exposure controls/personal protection

Environmental exposure controls

: No special measures are required for small quantities under normal and intended conditions of product use.

Individual protection measures

Hygiene measures

: No special measures are required for small quantities under normal and intended conditions of product use.

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

: No special measures are required for small quantities under normal and intended conditions of product use.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

: No special measures are required for small quantities under normal and intended conditions of product use.

Section 9. Physical and chemical properties

Appearance

Physical state : Liquid. [Paste.]

Color : Various

Odor : Fruity ester-like **Odor threshold** : Not available. : Not available. **Melting point** : Not available. **Boiling point** : Not available. Flash point : Not available. : Not available. **Evaporation rate** Flammability (solid, gas) : Not applicable. Lower and upper explosive : Not available.

(flammable) limits

Vapor pressure : Not available.
Vapor density : Not available.
Relative density : 2.5 [Water = 1]

Solubility : Insoluble in the following materials: cold water and hot water.

Solubility in water : Not available.

Partition coefficient: n- : Not available.

octanol/water

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Premise Flowable

Section 9. Physical and chemical properties

Auto-ignition temperature: Not available.Decomposition temperature: Not available.SADT: Not available.Viscosity: Not available.

Section 10. Stability and reactivity

Reactivity: No specific test data related to reactivity available for this product or its ingredients.

Chemical stability: The product is stable.

Possibility of hazardous reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

Under normal conditions of storage and use, hazardous polymerization will not occur.

Conditions to avoid : Keep away from heat and direct sunlight. Heat can cause polymerization with rapid

release of energy.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials and reducing

materials.

Amine. Peroxide.

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should

not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

| Product/ingredient name | Result | Species | Dose | Exposure |
|--|-----------|---------|-------------|----------|
| 3-trimethoxysilylpropyl methacrylate | LD50 Oral | Rat | 23504 mg/kg | - |
| 2,2'-ethylenedioxydiethyl dimethacrylate | LD50 Oral | Rat | 10837 mg/kg | - |

Conclusion/Summary : Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO 10993-5.

Irritation/Corrosion

| Product/ingredient name | Result | Species | Score | Exposure | Observation |
|-------------------------|----------------------|---------|-------|-------------------------|-------------|
| 3-trimethoxysilylpropyl | Eyes - Mild irritant | Rabbit | - | 24 hours 500 | - |
| methacrylate | Skin - Mild irritant | Rabbit | - | milligrams 24 hours 500 | - |
| | | | | milligrams | |

Sensitization

Not available.

Conclusion/Summary

Skin : Kligman score: Grade I (weak sensitizer)

Mutagenicity

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Section 11. Toxicological information

Not available.

Conclusion/Summary

: Not mutagenic in Ames test.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

| Name | Category | Route of exposure | Target organs |
|---|------------|-------------------|------------------------------|
| Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]- | Category 3 | Not applicable. | Respiratory tract irritation |
| 2,2'-ethylenedioxydiethyl dimethacrylate | Category 3 | Not applicable. | Respiratory tract irritation |
| 2-ethylhexyl 4-(dimethylamino)benzoate | Category 3 | Not applicable. | Respiratory tract irritation |

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely

routes of exposure

: Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : Causes serious eye irritation.Inhalation : May cause respiratory irritation.

Skin contact : Causes skin irritation.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact: Adverse symptoms may include the following:

pain or irritation watering redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

Skin contact: Adverse symptoms may include the following:

irritation redness

Ingestion: No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

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Section 11. Toxicological information

Short term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Long term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.
 Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Teratogenicity : No known significant effects or critical hazards.
 Developmental effects : No known significant effects or critical hazards.
 Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Not available.

Section 12. Ecological information

Toxicity

Not available.

Persistence and degradability

Not available.

Bioaccumulative potential

| Product/ingredient name | LogP _{ow} | BCF | Potential |
|--|--------------------|------|-----------|
| Poly(oxy-1,2-ethanediyl), α,α' - [(1-methylethylidene)di-4,1- phenylene]bis[ω -[(2-methyl-1- oxo-2-propen-1-yl)oxy]- | 3.43 to 5.62 | 2372 | high |
| 3-trimethoxysilylpropyl methacrylate | 2.1 | - | low |
| 2,2'-ethylenedioxydiethyl dimethacrylate | 1.88 | - | low |
| 2-ethylhexyl 4- (dimethylamino)benzoate | 5.77 | - | high |

Mobility in soil

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Premise Flowable

Section 12. Ecological information

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Section 14. Transport information

| | DOT Classification | IMDG | IATA |
|----------------------------|--------------------|----------------|----------------|
| UN number | Not regulated. | Not regulated. | Not regulated. |
| UN proper shipping name | - | - | - |
| Transport hazard class(es) | - | - | - |
| Packing group | - | - | - |
| Environmental hazards | No. | No. | No. |
| Additional information | - | - | - |

Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

: Not available.

Section 15. Regulatory information

U.S. Federal regulations

: TSCA 8(a) PAIR: mequinol; oxybenzone

United States inventory (TSCA 8b): All components are listed or exempted.

Clean Water Act (CWA) 307: zinc oxide; zinc hexafluorosilicate

Clean Water Act (CWA) 311: zinc hexafluorosilicate

Clean Air Act Section 112

(b) Hazardous Air **Pollutants (HAPs)** : Listed

Clean Air Act Section 602

: Not listed

Class I Substances

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Section 15. Regulatory information

Clean Air Act Section 602

: Not listed

Class II Substances

DEA List I Chemicals

: Not listed

(Precursor Chemicals)

DEA List II Chemicals (Essential Chemicals)

: Not listed

(Lessential Orienticals

SARA 302/304

Composition/information on ingredients

| | | | SARA 302 TPQ | | SARA 304 RQ | |
|----------------|---------|------|--------------|-----------|-------------|-----------|
| Name | % | EHS | (lbs) | (gallons) | (lbs) | (gallons) |
| ethylene oxide | <0.0188 | Yes. | 1000 | - | 10 | - |

SARA 304 RQ : 59101.7 lbs / 26832.2 kg [2835.3 gal / 10732.9 L]

SARA 311/312

Classification : Immediate (acute) health hazard

Composition/information on ingredients

| Name | % | Fire hazard | Sudden release of pressure | Reactive | Immediate (acute) health hazard | Delayed (chronic) health hazard |
|---|-------|----------------|----------------------------------|----------|--|--|
| Poly(oxy-1,2-ethanediyl), α,α'-[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]- | 10-30 | No. | No. | No. | Yes. | No. |
| 3-trimethoxysilylpropyl methacrylate | 5-10 | No. | No. | No. | Yes. | No. |
| 2,2'-ethylenedioxydiethyl dimethacrylate | 5-10 | Yes. | No. | No. | Yes. | No. |
| 2-ethylhexyl 4-(dimethylamino) benzoate | 1-5 | No. | No. | No. | Yes. | No. |

SARA 313

Not applicable.

State regulations

Massachusetts : The following components are listed: MINERAL WOOL FIBER

New York : None of the components are listed.

New Jersey : The following components are listed: FLUORIDES

Pennsylvania : None of the components are listed.

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

| Ingredient name | Cancer | • | level | Maximum acceptable dosage level |
|------------------------------------|--------|---|-------|---------------------------------|
| ethylene oxide Titanium dioxide | | | | Yes. No. |

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Section 16. Other information

Hazardous Material Information System (U.S.A.)



Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks Although HMIS® ratings are not required on SDSs under 29 CFR 1910. 1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.)



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

History

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Version : 1
Prepared by : IHS

Key to abbreviations

: ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships,

1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations

References : HCS (U.S.A.)- Hazard Communication Standard

International transport regulations

✓ Indicates information that has changed from previously issued version.

Notice to reader

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Section 16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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