

MEDICEPT UK LTD

Material Safety Data Sheet

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

Revision Date: 05th September 2008

SECTION 1

Product & Company identification

1.1 Product name

FLOW PLUS (all shades)

1.2 Uses/Application:

Dental restorative material.

1.3 Company (Name, address and info phone number)

MEDICEPT UK LTD

2nd Floor, Hygeia House, 66 College Road, Harrow, Middlesex HA1 1BE. UK

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

Tel: +44 (0)1923 251327 (08.00-17.00, European time, GMT 0:00)

E-mail address: info@mediceptdental.co.uk

SECTION 2

Hazard identification

2.1 Hazard classification (according to communitarian directives 67/548/EEC & 99/45/EC)

None.

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 Hazardous ingredients

HAZARDOUS INGREDIENTS	%	HAZARD SYMBOLS	RISK PHRASES	CAS N.	EINECS N.
Zinc Oxide (ZnO)	< 0,1	N	50-53	1314-13-2	215-222-5

3.2 Other non-hazardous ingredients

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

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: 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 - get medical attention if discomfort persists.
- 4.4 Treatment for ingestion (swallowing): 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.
- 5.3 Special fire fighting measures: 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.
- 6.2 Environmental Precautions: Material should not be allowed to drain into sewers.
- 6.3 Reclaiming Methods: Absorb 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:	TiO ₂ : PEL/TLV 3,1ppm (10mg/m ³); ZnO: TWA: 0,6 ppm (2 mg/m ³); TLV: 3 ppm (10 mg/m ³)
8.2 Exposure control measures	
8.2.1 Precautionary Measures: (according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)	
Ventilation:	Local Exhaust Ventilation: Good general ventilation should be sufficient to control airborne levels of vapours released by 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.
<i>Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC)</i>	
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 environment	
pH: Not available	Relative density: Not determined
Boiling point: Not determined (N/D)	Specific gravity: 2,5 g/ml
Flash point: Not determined	Solubility: Insoluble
Flammability: Not flammable.	Partition coefficient n-octanol/water: N/D
Lower Explosivity Limit (L.E.L.): N/A	Viscosity: Not determined
Upper Explosivity Limit (U.E.L.): N/A	Vapour density (air = 1): Not determined
Oxidizing properties: None	Evaporation rate (n-butane = 1): Not determined
Vapour pressure: 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

Stabilizers: 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.

Effects and hazards of Inhalation (Breathing): 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.

Toxic-kinetic effects: 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
ZnO (Acute toxicity):	LD ₅₀ (oral mouse)	7950 mg/Kg

	LD ₅₀ (skin rat)	> 2000 mg/Kg
	LD _{Lo} (oral human)	500 mg/Kg
	LC ₅₀ (inhalation rat/4hrs)	> 5700 mg/m ³ (4 hrs)

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)
ZnO	EC ₅₀ (Daphnia magna)	> 1000 mg/l (48 hrs)
	LC ₅₀ (Oncorhynchus mykiss)	1,1 mg/l (96 hrs)
	LC ₅₀ (Lepomis macrochirus)	> 320 mg/l (96 hrs)
	LC ₅₀ (Pimephales promelas)	2246 mg/l (96 hrs)
	EC ₅₀ (Selenastrum capricornutum)	0,17 mg/l (72 hr; Lisec 1997)

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

50/53 Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.

16.1.1 Safety phrases of all ingredients

2 Keep out of the reach of children.

61 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.O.S.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:

67/548/EEC:	Classification, packaging and labelling of dangerous substances.
99/45/EC:	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.
2001/58/EC:	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).
89/656/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).
89/686/EEC:	Approximation of the laws of the Member States relating to personal protective equipment.
94/9/EC:	Approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres
98/24/EC:	Protection of the health and safety of workers from the risks related to chemical agents at work.

Document modification history: 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.