

Printing date 04/20/2015 Version number 7 Reviewed on 03/30/2015

## 1 Identification

- · Product identifier
- · Trade name: Compoglass F
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Light-curing, componer-based dental restorative material
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

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- · Information department: Quality Assurance / Regulatory Affairs
- · Emergency telephone number: 24 Hour Emergency Assistance:

Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

## 2 Hazard(s) identification

· Classification of the substance or mixture

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

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

STOT SE 3 H335 May cause respiratory irritation.

- · Label elements
- · GHS label elements

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

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labeling:

urethane dimethacrylate ytterbium trifluoride

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cycloaliphatic dicarboxylic acid dimethacrylate polyethylene glycol dimethacrylate

### · Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

### · Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

Wash contaminated clothing before reuse.

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

If eye irritation persists: Get medical advice/attention.

## · Additional information:

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

- · Hazard description:
- · WHMIS-symbols:

D2B - Toxic material causing other toxic effects



- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



1 Health = 1Fire = 0

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

# 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.

| · Dangerous components: |   |        |
|-------------------------|---|--------|
| 13760-80-0              | ytterbium trifluoride                           | 10-13% |
| 72869-86-4              | urethane dimethacrylate                         | 5-<10% |
|                         | cycloaliphatic dicarboxylic acid dimethacrylate | 3-7%   |
| 25852-47-5              | polyethylene glycol dimethacrylate              | 3-5%   |

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## 4 First-aid measures

- · Description of first aid measures
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

*In case of unconsciousness place patient stably in side position for transportation.* 

- · After skin contact: Rinse with water.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, 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: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

## 7 Handling and storage

- · Handling:
- · Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry 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: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Protect from exposure to the light.

Protect from heat and direct sunlight.

Keep receptacle tightly sealed.

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· 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:

Usual hygienic measures for dental practice.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the skin.

- · Breathing equipment: Not required.
- · Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

# 9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Pasty

Color: According to product specification

Odor: CharacteristicOdour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined.

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|                                     |   | (Contd. of page |
|-------------------------------------|---|-----------------|
| Boiling point/Boiling range:        | Undetermined.                                 |                 |
| · Flash point:                      | Not applicable.                               |                 |
| Flammability (solid, gaseous):      | Not applicable.                               |                 |
| Auto igniting:                      | Product is not selfigniting.                  |                 |
| Danger of explosion:                | Product does not present an explosion hazard. |                 |
| Explosion limits:                   |   |                 |
| Lower:                              | Not determined.                               |                 |
| Upper:                              | Not determined.                               |                 |
| Vapor pressure:                     | Not determined.                               |                 |
| Density at 20 °C:                   | 2.2 g/cm³                                     |                 |
| Relative density                    | Not determined.                               |                 |
| Vapour density                      | Not determined.                               |                 |
| Evaporation rate                    | Not determined.                               |                 |
| Solubility in / Miscibility with    |   |                 |
| Water:                              | Nearly insoluble.                             |                 |
| Partition coefficient (n-octanol/wa | t <b>er):</b> Not determined.                 |                 |
| 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

Stable under normal handling and storage conditions.

Photoreactive (Danger of polymerization).

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid

Protect from exposure to the light.

Keep away from heat and direct sunlight.

- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: None under normal conditions of storage and use.

# 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: No further relevant information available.

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- · Carcinogenic categories
- · NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

# 12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative 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

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 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:

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

| · UN-Number  |      |  |
|--|------|--|
| · DOT, TDG, ADN, IMDG, IATA                              | Void |  |
| · UN proper shipping name<br>· DOT, TDG, ADN, IMDG, IATA | Void |  |
| · Transport hazard class(es)                             |      |  |
| · DOT, TDG, ADN, IMDG, IATA                              |      |  |
| ·Class   | Void |  |
| · Packing group  |      |  |
| · DOT, TDG, IMDG, IATA                                   | Void |  |
| · Environmental hazards:                                 |      |  |
| · Marine pollutant:                                      | No   |  |

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|--|--|
| · Special precautions for user   | Not applicable.  |
| · Transport in bulk according to Annex I<br>MARPOL73/78 and the IBC Code | <b>I of</b><br>Not applicable.   |
| · Transport/Additional information:                                      | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN ''Model Regulation'':   | -  |

# 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 is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

13760-80-0 ytterbium trifluoride

A4

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

None of the ingredients is listed.

· GHS label elements

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

· Hazard pictograms



· Signal word Warning

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### · Hazard-determining components of labeling:

urethane dimethacrylate ytterbium trifluoride cycloaliphatic dicarboxylic acid dimethacrylate polyethylene glycol dimethacrylate

#### · Hazard statements

Causes skin irritation.

Causes serious eve irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

### · Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

Wash contaminated clothing before reuse.

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

If eye irritation persists: Get medical advice/attention.

## · National regulations:

## · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

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

# 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### · Date of preparation / last revision 04/20/2015 / 6

## · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

 $DOT: \ US \ Department \ of \ Transportation$ 

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

 $WHMIS:\ Workplace\ Hazardous\ Materials\ Information\ System\ (Canada)$ 

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

\* Data compared to the previous version altered.

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