

## Safety data sheet according to UK REACH

Printing date 30.07.2024

Version number 5 (replaces version 4)

Revision: 30.07.2024

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** *UNIFAST III Liquid*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** *Auxillary for dental technology*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
GC EUROPE N.V.  
Interleuvenlaan 33  
B-3001 Leuven  
Tel. +32/(0)16/74.10.00  
Fax +32/(0)16/40.26.84  
msds@gc.dental
- **Further information obtainable from:** *Regulatory affairs*
- **1.4 Emergency telephone number:**  
*National poison center for United Kingdom of Great Britain and Northern Ireland:*  
*Belfast: +44 28 90 63 2032*  
*Birmingham: +44 121 507 4123*  
*Edinburgh: +44 131 242 1383*  
*Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180*  
*Penarth: +44 292 071 55 54*

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*Flam. Liq. 2            H225 Highly flammable liquid and vapour.*  
*Skin Irrit. 2            H315 Causes skin irritation.*  
*Skin Sens. 1            H317 May cause an allergic skin reaction.*  
*STOT SE 3            H335 May cause respiratory irritation.*  
*Aquatic Chronic 3    H412 Harmful to aquatic life with long lasting effects.*
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
*The product is classified and labelled according to the GB CLP regulation.*
- **Exemptions**  
*The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).*
- **Hazard pictograms**



GHS02    GHS07

- **Signal word** *Danger*

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**Trade name: UNIFAST\_III\_Liquid**

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**· Hazard-determining components of labelling:**

Methyl methacrylate

Ethyleneglycol dimethacrylate

2-(2H-benzotriazol-2-yl)-p-cresol

**· Hazard statements**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

**· Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

### SECTION 3: Composition/information on ingredients

**· 3.2 Mixtures****· Description:**

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

**· Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Index number: 607-035-00-6	Methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335 substance with a Community workplace exposure limit	90-<100%
CAS: 99-97-8 EINECS: 202-805-4 Index number: 612-296-00-4	N,N-dimethyl-p-toluidine Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; STOT RE 2, H373; Aquatic Chronic 3, H412 ATE: LD50 oral: 140 mg/kg LC50/4 h inhalative: 1.4 mg/l	2.5-<5%
CAS: 97-90-5 EINECS: 202-617-2 Index number: 607-114-00-5	Ethyleneglycol dimethacrylate Skin Sens. 1, H317; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: C ≥ 10 %	1-<2.5%
CAS: 3290-92-4 EINECS: 221-950-4	Propylidynetrimethyl trimethacrylate Aquatic Chronic 2, H411	1-<2.5%

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CAS: 2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	(Contd. of page 2) ≥0.25-<0.5%
EINECS: 219-470-5	Acute Tox. 3, H331; Aquatic Chronic 1, H410; Skin Sens. 1, H317	
CAS: 128-37-0	Butylated hydroxytoluene	0.1-<0.2%
EINECS: 204-881-4	Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Substance identified as having endocrine disrupting properties (II)	

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

#### · 4.1 Description of first aid measures

##### · **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

If symptoms persist consult doctor.

##### · **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

Do not use mouth to mouth or mouth to nose resuscitation.

Take affected persons into fresh air and keep quiet.

##### · **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

If skin irritation continues, consult a doctor.

##### · **After eye contact:**

Rinse opened eye for several minutes under running water.

If symptoms persist consult doctor.

##### · **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

#### · 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions

#### · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

### SECTION 5: Firefighting measures

#### · 5.1 Extinguishing media

· **Suitable extinguishing agents:** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.

· **For safety reasons unsuitable extinguishing agents:** Water

#### · 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

No further relevant information available.

#### · 5.3 Advice for firefighters

##### · **Protective equipment:**

Mouth respiratory protective device.

Wear self-contained respiratory protective device.

##### · **Additional information**

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

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### SECTION 6: Accidental release measures

#### · 6.1 Personal precautions, protective equipment and emergency procedures

Remove persons from danger area.  
Keep away from ignition sources.  
Avoid contact with the eyes and skin.  
Wear protective clothing.

#### · 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.  
Do not allow to penetrate the ground/soil.

#### · 6.3 Methods and material for containment and cleaning up:

Ensure adequate ventilation.  
Absorb liquid components with liquid-binding material.  
Dispose of the material collected according to regulations.

#### · 6.4 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.

### SECTION 7: Handling and storage

#### · 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.  
Avoid contact with the eyes and skin.

#### · Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.  
Do not spray onto a naked flame or any incandescent material.

#### · 7.2 Conditions for safe storage, including any incompatibilities

##### · Storage:

##### · Requirements to be met by storerooms and receptacles:

Store in a cool location.  
Store only in unopened original receptacles.

##### · Information about storage in one common storage facility: Store away from foodstuffs.

##### · Further information about storage conditions:

Keep container tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.  
Protect from heat and direct sunlight.  
Store in a cool place.

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

### SECTION 8: Exposure controls/personal protection

#### · 8.1 Control parameters

##### · Ingredients with limit values that require monitoring at the workplace:

##### 80-62-6 Methyl methacrylate

WEL	Short-term value: 416 mg/m <sup>3</sup> , 100 ppm
	Long-term value: 208 mg/m <sup>3</sup> , 50 ppm

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· <b>DNELs</b>		
<b>80-62-6 Methyl methacrylate</b>		
Dermal	DNEL dermal	13.67 mg/kg bw/day (man) (worker, l. te., syst.)
Inhalative	DNEL inhalation	208 mg/m3 (air) (worker, l. te., syst.)
<b>128-37-0 Butylated hydroxytoluene</b>		
Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 mg/m3 (man)
· <b>PNECs</b>		
<b>99-97-8 N,N-dimethyl-p-toluidine</b>		
PNEC Aqua	152.59 µg/L (freshwater)	
<b>3290-92-4 Propylidynetrimethyl trimethacrylate</b>		
PNEC Aqua	2.76 µg/L (freshwater) 20 µg/L (intermittent releases) 0.276 µg/L (marine water)	
PNEC STP	10 mg/L (Sewage Treatment Plants)	
PNEC Sediment	0.4951 mg/kg sed dw (freshwater) 0.04951 mg/kg sed dw (marine water)	
PNEC Air	mg/L (air)	
PNEC Soil	0.0974 mg/kg soil dw (soil)	
PNEC Predator	mg/kg (Predator)	

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

· **Respiratory protection:** Suitable respiratory protective device recommended.

· **Hand protection**



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.

· **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.

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### · Eye/face protection



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

### · 9.1 Information on basic physical and chemical properties

#### · General Information

· Physical state	Fluid
· Colour:	Clear
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	100 °C
· Flammability	Highly flammable.
· Lower and upper explosion limit	
· Lower:	2.1 Vol %
· Upper:	12.5 Vol %
· Flash point:	10 °C
· Auto-ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	0.9 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not determined.

### · 9.2 Other information

· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· VOC (EC)	0.0 g/l
· Change in condition	
· Evaporation rate	Not determined.

### · Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void

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· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Highly flammable liquid and vapour.
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

#### · **LD/LC50 values relevant for classification:**

##### **80-62-6 Methyl methacrylate**

Oral	LD50	6,000 mg/kg (rabbit)
Dermal	LD50	>5,000 mg/kg (rab)
Inhalative	LC50/4 h	29.8 mg/l (rat (f+m))

##### **99-97-8 N,N-dimethyl-p-toluidine**

Oral	LD50	140 mg/kg (ATE) 1,650 mg/kg (rat (f+m))
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	1.4 mg/l (ATE) 1.4 mg/l (rat (f+m))

##### **97-90-5 Ethyleneglycol dimethacrylate**

Oral	LD50	8,700 mg/kg (rat (f+m))
Dermal	LD50	>2,000 mg/kg (rat (f+m))

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**2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol**

Oral LD50 10,000 mg/kg (rat (f+m))

Inhalative LC50/4 h 0.59 mg/l (rat (f+m))

**128-37-0 Butylated hydroxytoluene**

Oral LD50 &gt;6,000 mg/kg (rat (f+m)) (OECD 401)

- **Skin corrosion/irritation** Causes skin irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **STOT-single exposure** May cause respiratory irritation.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

128-37-0 Butylated hydroxytoluene

List II

**SECTION 12: Ecological information**

- **12.1 Toxicity**

- **Aquatic toxicity:**

**99-97-8 N,N-dimethyl-p-toluidine**

LC50/96h 46 mg/L (fish)

**3290-92-4 Propylidynetrimethyl trimethacrylate**

LC50/96h (dynamic) &gt;1 mg/L (Oncorhynchus mykiss) (OECD Guideline 203 (Fish, Acute Toxicity Test))

**128-37-0 Butylated hydroxytoluene**

EC50/48h (static) 0.48 mg/l (daphnia magna) (OECD 202)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (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.  
Harmful to aquatic organisms

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**

- **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

· <b>14.1 UN number or ID number</b> · <b>ADR, IMDG, IATA</b>	UN1247
· <b>14.2 UN proper shipping name</b> · <b>ADR</b> · <b>IMDG, IATA</b>	1247 METHYL METHACRYLATE MONOMER, STABILIZED METHYL METHACRYLATE MONOMER, STABILIZED
· <b>14.3 Transport hazard class(es)</b> · <b>ADR</b>	
	
· <b>Class</b> · <b>Label</b>	3 (F1) Flammable liquids. 3
· <b>IMDG, IATA</b>	
	
· <b>Class</b> · <b>Label</b>	3 Flammable liquids. 3
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	II
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b> · <b>Hazard identification number (Kemler code):</b> · <b>EMS Number:</b> · <b>Stowage Category</b> · <b>Stowage Code</b>	Warning: Flammable liquids. 33 F-E,S-D C SW1 Protected from sources of heat. SW2 Clear of living quarters.
· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b>	2

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· <b>Tunnel restriction code</b>	D/E
· <b>IMDG</b>	1L
· <b>Limited quantities (LQ)</b>	Code: E2
· <b>Excepted quantities (EQ)</b>	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Poisons Act**

- **Regulated explosives precursors**

None of the ingredients is listed.

- **Regulated poisons**

None of the ingredients is listed.

- **Reportable explosives precursors**

None of the ingredients is listed.

- **Reportable poisons**

None of the ingredients is listed.

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **Seveso category P5c FLAMMABLE LIQUIDS**

- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t

- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

- **Relevant phrases**

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

- **Classification according to Regulation (EC) No 1272/2008** Calculation method

- **Department issuing SDS:** Regulatory affairs

- **Contact:** msds@gc.dental

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### · **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (UK REACH)

PNEC: Predicted No-Effect Concentration (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

ATE: Acute toxicity estimate values

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 3: Acute toxicity – Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

### · **Sources**

• ECHA (<http://echa.europa.eu/>)

• EnviChem ([www.echemportal.org](http://www.echemportal.org))

### · **\* Data compared to the previous version altered.**

This version replaces all previous versions.

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

· **Trade name:** *UNIFAST III Powder*

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
*No further relevant information available.*

· **Application of the substance / the mixture** *Auxillary for dental technology*

#### 1.3 Details of the supplier of the safety data sheet

· **Manufacturer/Supplier:**

*GC EUROPE N.V.*

*Interleuvenlaan 33*

*B-3001 Leuven*

*Tel. +32/(0)16/74.10.00*

*Fax +32/(0)16/40.26.84*

*msds@gc.dental*

· **Further information obtainable from:** *Regulatory affairs*

#### 1.4 Emergency telephone number:

*National poison center for United Kingdom of Great Britain and Northern Ireland:*

*Belfast: +44 28 90 63 2032*

*Birmingham: +44 121 507 4123*

*Edinburgh: +44 131 242 1383*

*Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180*

*Penarth: +44 292 071 55 54*

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

· **Classification according to Regulation (EC) No 1272/2008**

*The product is not classified, according to the GB CLP regulation.*

#### 2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008** *Void*

#### Exemptions

*The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).*

· **Hazard pictograms** *Void*

· **Signal word** *Void*

· **Hazard statements** *Void*

#### Additional information:

*Safety data sheet available on request.*

#### 2.3 Other hazards

· **Results of PBT and vPvB assessment**

· **PBT:** *Not applicable.*

· **vPvB:** *Not applicable.*

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### SECTION 3: Composition/information on ingredients

#### · 3.2 Mixtures

#### · Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

#### · Dangerous components:

CAS: 13463-67-7 EINECS: 236-675-5 Index number: 022-006-00-2	titanium dioxide	Carc. 2, H351 substance with a Community workplace exposure limit	0.5-<1%
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· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

#### · 4.1 Description of first aid measures

· **General information:** If symptoms persist consult doctor.

#### · After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

· **After skin contact:** If skin irritation continues, consult a doctor.

#### · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

#### · After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### SECTION 5: Firefighting measures

#### · 5.1 Extinguishing media

#### · Suitable extinguishing agents:

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire extinguishing methods suitable to surrounding conditions.

· **For safety reasons unsuitable extinguishing agents:** Water with full jet

#### · 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

No further relevant information available.

#### · 5.3 Advice for firefighters

· **Protective equipment:** Wear self-contained respiratory protective device.

#### · Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

### SECTION 6: Accidental release measures

#### · 6.1 Personal precautions, protective equipment and emergency procedures

Remove persons from danger area.

Avoid formation of dust.

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*Wear protective clothing.*

- **6.2 Environmental precautions:**

*Do not allow product to reach sewage system or any water course.**Do not allow to penetrate the ground/soil.*

- **6.3 Methods and material for containment and cleaning up:**

*Pick up mechanically.**Prevent formation of dust.**Dispose of the material collected according to regulations.*

- **6.4 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.*

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**

*Prevent formation of dust.**Any unavoidable deposit of dust must be regularly removed.*

- **Information about fire - and explosion protection:** *Dust can combine with air to form an explosive mixture.*

- **7.2 Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** *Store only in unopened original receptacles.*

- **Information about storage in one common storage facility:** *Store away from foodstuffs.*

- **Further information about storage conditions:** *None.*

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

### SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

**13463-67-7 titanium dioxide**WEL Long-term value: 10\* 4\*\* mg/m<sup>3</sup>

\*total inhalable \*\*respirable

- **DNELs**

**13463-67-7 titanium dioxide**Inhalative DNEL inhalation 10 mg/m<sup>3</sup> (man)

- **Additional information:** *The lists valid during the making were used as basis.*

- **8.2 Exposure controls**

- **Appropriate engineering controls** *No further data; see section 7.*

- **Individual protection measures, such as personal protective equipment**

- **General protective and hygienic measures:**

*The usual precautionary measures are to be adhered to when handling chemicals.**Do not inhale dust / smoke / mist.**Wash hands before breaks and at the end of work.*

- **Respiratory protection:** *Suitable respiratory protective device recommended.*

- **Hand protection** *Protective gloves*

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· **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/face protection** Safety glasses

### SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Solid

· **Colour:**

According to product specification

· **Odour:**

Nearly odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Not determined.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable.

· **Auto-ignition temperature:**

Undetermined.

· **Decomposition temperature:**

Not determined.

· **pH**

Not applicable.

· **Viscosity:**

· **Kinematic viscosity**

Not applicable.

· **Dynamic:**

Not applicable.

· **Solubility**

· **water:**

Insoluble.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not applicable.

· **Density and/or relative density**

· **Density at 20 °C:**

1.2 g/cm<sup>3</sup>

· **Relative density**

Not determined.

· **Vapour density**

Not applicable.

· **Particle characteristics**

SiO<sub>2</sub>: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-based)  
Diameter agglomerate = 5 - 50 µm (laser diffraction dry module, d50, volume based)

· **9.2 Other information**

· **Appearance:**

· **Form:**

Solid

· **Important information on protection of health and environment, and on safety.**

· **Ignition temperature:**

Product is not selfigniting.

· **Explosive properties:**

Product does not present an explosion hazard.

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- **Change in condition**
- **Evaporation rate** Not applicable.

- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

#### · LD/LC50 values relevant for classification:

##### 13463-67-7 titanium dioxide

Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
Inhalative	LC50/4 h	>6.82 mg/l (rat male)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **11.2 Information on other hazards**

· <b>Endocrine disrupting properties</b>
--

None of the ingredients is listed.
------------------------------------

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (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.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |               |
|---|---------------|
| · <b>14.1 UN number or ID number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                       | not regulated |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | not regulated |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | not regulated |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | not regulated |

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- |   |                 |
|---|-----------------|
| <b>· 14.5 Environmental hazards:</b>                                  |                 |
| <b>· Marine pollutant:</b>  | No              |
| <b>· 14.6 Special precautions for user</b>                            | Not applicable. |
| <b>· 14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| <b>· UN "Model Regulation":</b>                                       | not regulated   |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Poisons Act**

<b>· Regulated explosives precursors</b>
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None of the ingredients is listed.
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<b>· Regulated poisons</b>
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None of the ingredients is listed.
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<b>· Reportable explosives precursors</b>
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None of the ingredients is listed.
------------------------------------

<b>· Reportable poisons</b>
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None of the ingredients is listed.
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- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

- **Relevant phrases**  
H351 Suspected of causing cancer.
- **Classification according to Regulation (EC) No 1272/2008** Calculation method
- **Department issuing SDS:** Regulatory affairs
- **Contact:** msds@gc.dental
- **Abbreviations and acronyms:**  
 ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  
 IMDG: International Maritime Code for Dangerous Goods  
 IATA: International Air Transport Association  
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
 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)  
 DNEL: Derived No-Effect Level (UK REACH)  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative  
 Carc. 2: Carcinogenicity – Category 2
- **Sources**
  - ECHA (<http://echa.europa.eu/>)
  - EnviChem ([www.echemportal.org](http://www.echemportal.org))

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