

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 23.09.2016

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

- **1.1 Product identifier**
  - **Trade name:** *GC Essentia Light and Dark Enamel, Opalescent Modifier*
- **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**

*Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.*

*Eye Irrit. 2 H319 Causes serious eye irritation.*

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

- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**

*Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.*

*The product is classified and labelled according to the CLP regulation.*
  - **Hazard pictograms**



GHS07

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**

*2,2'-ethylenedioxydiethyl dimethacrylate*  
*(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate*  
*Urethane Dimethacrylate (UDMA)*

(Contd. on page 2)

GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 23.09.2016

**Trade name: GC Essentia Light and Dark Enamel, Opalescent Modifier**

(Contd. of page 1)

1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde

· **Hazard statements**

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P280 Wear protective gloves / eye protection / face protection.

P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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 Chemical characterisation: 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: 41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid. Aquatic Chronic 4, H413	10-<25%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	2.5-<5%
CAS: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) Skin Sens. 1, H317	1-<2.5%
CAS: 1565-94-2 EINECS: 216-367-7	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate Eye Dam. 1, H318; Skin Sens. 1, H317	1-<2.5%
CAS: 9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335	0.2-<0.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.1-<0.2%

· **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.

If symptoms persist consult doctor.

· **After inhalation:**

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

(Contd. on page 3)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 23.09.2016

**Trade name: GC Essentia Light and Dark Enamel, Opalescent Modifier**

(Contd. of page 2)

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:**

Protect unharmed eye.

Rinse opened eye for several minutes under running water. Then 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** 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>, 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.

· **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.

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.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

· **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.

GB

(Contd. on page 4)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 23.09.2016

Trade name: GC Essentia Light and Dark Enamel, Opalescent Modifier

(Contd. of page 3)

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Prevent formation of dust.  
Any unavoidable deposit of dust must be regularly removed.  
Avoid contact with the eyes and skin.
- **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

- **Additional information about design of technical facilities:** No further data; see item 7.

- **8.1 Control parameters**

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

128-37-0 Butylated hydroxytoluene	
WEL	Long-term value: 10 mg/m <sup>3</sup>

- **DNELs**

128-37-0 Butylated hydroxytoluene		
Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 mg/m <sup>3</sup> (man)

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

- **8.2 Exposure controls**

- **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.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing

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

- **Protection of hands:**



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.

(Contd. on page 5)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 23.09.2016

Trade name: GC Essentia Light and Dark Enamel, Opalescent Modifier

(Contd. of page 4)

· Eye protection:



Tightly sealed goggles

### SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Powder
Colour:	Light beige
Odour:	Alcohol-like
Odour threshold:	Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not determined.

· Ignition temperature: Undetermined.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapour pressure: Not applicable.

Density at 20 °C:	1.9 g/cm <sup>3</sup>
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.

· Solubility in / Miscibility with water: Insoluble.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic:	Not applicable.
Kinematic:	Not applicable.

· Solvent content:

Organic solvents:	0.0 %
-------------------	-------

(Contd. on page 6)

GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 23.09.2016

**Trade name: GC Essentia Light and Dark Enamel, Opalescent Modifier**

(Contd. of page 5)

- **9.2 Other information** No further relevant information available.

### 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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

**72869-86-4 Urethane Dimethacrylate (UDMA)**

Oral LD50 > 5000 mg/kg (rat female) (OECD 401)

**128-37-0 Butylated hydroxytoluene**

Oral LD50 > 6000 mg/kg (rat (f+m)) (OECD 401)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **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.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

**72869-86-4 Urethane Dimethacrylate (UDMA)**

EC50/48h (static) > 1.2 mg/l (daphnia magna) (OECD 202)

**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.

(Contd. on page 7)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 23.09.2016

**Trade name: GC Essentia Light and Dark Enamel, Opalescent Modifier**

(Contd. of page 6)

- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Danger to drinking water if even extremely small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### 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.

- **European waste catalogue**

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing hazardous substances

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

### SECTION 14: Transport information

<ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>	not regulated
<ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>	not regulated
<ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul>	not regulated
<ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>	not regulated
<ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>	No
<ul style="list-style-type: none"> <li>· <b>14.6 Special precautions for user</b></li> </ul>	Not applicable.
<ul style="list-style-type: none"> <li>· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b></li> </ul>	Not applicable.
<ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>	not regulated

GB

(Contd. on page 8)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 23.09.2016

**Trade name: GC Essentia Light and Dark Enamel, Opalescent Modifier**

(Contd. of page 7)

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **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**  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H335 May cause respiratory irritation.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.  
H413 May cause long lasting harmful effects to aquatic life.
- **Classification according to Regulation (EC) No 1272/2008** Calculation method
- **Department issuing SDS:** Regulatory affairs
- **Contact:** msds@gc.dental
- **Abbreviations and acronyms:**  
ADR: Accord européen sur le transport 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 (REACH)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Eye Dam. 1: Serious eye damage/eye irritation – Category 1  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
Skin Sens. 1: Skin sensitisation – Category 1  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3  
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 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4
- **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.

**Disclaimer:**

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.