

Printing date 18.10.2023 Version number 7 (replaces version 6) Revision: 18.10.2023

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

- · 1.1 Product identifier
- · Trade name: Essentia Light, Dark and Medium Dentin
- · 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:

International: +01-813-248-0585 (ChemTel Inc.)

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

Acute Tox. 4 H302 Harmful if swallowed. Acute Tox. 3 H331 Toxic if inhaled.

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

Aquatic Chronic 2 H411 Toxic 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





GHS06 GHS09

· Signal word Danger

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· Hazard-determining components of labelling:

Urethane Dimethacrylate (UDMA)

Ytterbium trifluoride

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

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

· Hazard statements

H302 Harmful if swallowed.

H331 Toxic if inhaled.

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

· 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.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P405 Store locked up.

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

· Additional information:

27.2 % of the mixture consists of component(s) of unknown toxicity.

Contains 27.2 % of components with unknown hazards to the aquatic environment.

- · 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 compone	ents:	
CAS: 72869-86-4	Urethane Dimethacrylate (UDMA)	25-<50%
EINECS: 276-957-5	Aquatic Chronic 2, H411; Skin Sens. 1B, H317	
CAS: 68611-44-9	Silane, dichlorodimethyl-, reaction products with silica	10-<25%
EINECS: 271-893-4	Nanoform: set including amorphous nanoforms	
	surface-treated nanoforms	
	Shape: Spheroidal	
	Structure: amorphous forms	
	Crystallinity: amorphous nanoform	
CAS: 1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate	5-<10%
EINECS: 217-856-8	Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 3290-92-4	Propylidynetrimethyl trimethacrylate	5-<10%
EINECS: 221-950-4	Aquatic Chronic 2, H411	
CAS: 13760-80-0	Ytterbium trifluoride	5-<10%
EINECS: 237-354-2	Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331	
CAS: 41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-	1-<2.5%
	methylprop-2-enoic acid.	
	Aquatic Chronic 4, H413	
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CAS: 9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde	0.5-<1%
	Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335	1
CAS: 2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	0.1-<0.2%
EINECS: 219-470-5	Acute Tox. 3, H331; Aquatic Chronic 1, H410; Skin Sens. 1, H317	1
4 1 10 0 1 1 C		

[·] 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 or oxygen; call for doctor.

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 a doctor.

· After swallowing:

Do not induce vomiting; call for medical help immediately.

Rinse out mouth and then drink plenty of water.

- · 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: CO2, 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: 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 contact with the eyes and skin.

Wear protective clothing.

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· 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:

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.

Do not inhale dust / smoke / mist.

Prevent formation of aerosols.

Avoid contact with the eyes and skin.

- Information about fire and explosion protection: Protect against electrostatic charges.
- · 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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

PNECs		
3290-92-4 Propylidynetrimethyl trimethacrylate		
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	VEC 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.

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- · 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.

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.

· 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: According to product specification

Odour:
 Odour threshold:
 Melting point/freezing point:
 Boiling point or initial boiling point and boiling range
 Flammability
 Odour less
 Not determined.
 Undetermined.
 Not applicable.

· Lower and upper explosion limit

Not determined.

Upper:
Not determined.

Flash point:
Auto-ignition temperature:
Undetermined.
Undetermined.

· Auto-ignition temperature:
 Decomposition temperature:
 Not determined.
 PH
 Not determined.

· Viscosity:

• Kinematic viscosity Not determined. • Dynamic: Not determined.

· Solubility

· water: Insoluble.

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Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Particle characteristics	SiO2: Diameter particle structure = 2.5 - 50 nm (TEM)
	d50, number-based)
	Diameter agglomerate = 5 - 50 mm (laser diffraction di
	module, d50, volume based)
	68611-44-9 Silane, dichlorodimethyl-, reaction produc
	with silica:
	set including amorphous nanoforms
	surface-treated nanoforms
	Shape: Spheroidal
	Structure: amorphous forms
	Crystallinity: amorphous nanoform
9.2 Other information	
Appearance:	
Form:	Pasty
Important information on protection of health a environment, and on safety.	and
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
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 ga	ses
in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void

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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

Harmful if swallowed.

Toxic if inhaled.

· LD/LC50	· LD/LC50 values relevant for classification:		
72869-86-	72869-86-4 Urethane Dimethacrylate (UDMA)		
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)	
2440-22-4	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))	

- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Additional toxicological information:
- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

· 11.2 Information on other hazards

· Endocrine	e disrupting properties
128-37-0	Rutylated hydroxytoluene

List II

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity:

72869-86-4 Urethane Dimethacrylate (UDMA)

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

3290-92-4 Propylidynetrimethyl trimethacrylate

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

- · 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.

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- · 12.7 Other adverse effects
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground. 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.

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

14.1 UN number or ID number ADR, IMDG, IATA	UN2810
14.2 UN proper shipping name ADR	2810 TOXIC LIQUID, ORGANIC, N.O.S. (Ytterbiud trifluoride), ENVIRONMENTALLY HAZARDOUS
IMDG	TOXIC LIQUID, ORGANIC, N.O.S. (Ytterbium trifluorid Urethane Dimethacrylate (UDMA)), MARINE POLLUTANI
IATA	TOXIC LIQUID, ORGANIC, N.O.S. (Ytterbium trifluoride)
14.3 Transport hazard class(es)	
ADR	
Class	6.1 (T1) Toxic substances.
Label	6.1
· IMDG	
Class	6.1 Toxic substances.
Label	6.1

— GB

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IATA	
· Class	6.1 Toxic substances.
· Label	6.1
· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards: · Marine pollutant:	Product contains environmentally hazardous substances: 2 (2H-benzotriazol-2-yl)-p-cresol No
•	Symbol (fish and tree)
Special marking (ADR):	Symbol (fish and tree)
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category · Stowage Code	Warning: Toxic substances. 60 F-A,S-A A SW2 Clear of living quarters.
· 14.7 Maritime transport in bulk according to IM instruments	Not applicable.
Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ) · Transport category	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml 2
· Tunnel restriction code	<i>E</i>
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 2810 TOXIC LIQUID, ORGANIC, N.O.S. (YTTERBIUM TRIFLUORIDE), 6.1, III, ENVIRONMENTALL HAZARDOUS

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.

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· 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

H2 ACUTE TOXIC

E2 Hazardous to the Aquatic Environment

- Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H410 Very toxic to aquatic life with long lasting effects.

H411 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 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)

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

Acute Tox. 3: Acute toxicity - Category 3

Acute Tox. 4: Acute toxicity - Category 4

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

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

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Skin Sens. 1B: Skin sensitisation — Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) — Category 3
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 4: Hazardous to the aquatic environment - long-term aquatic hazard — Category 4

· Sources

- ECHA (http://echa.europa.eu/)
- EnviChem (www.echemportal.org)
- * * Data compared to the previous version altered.

This version replaces all previous versions.

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