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### 1 Identification of the substance or mixture and of the supplier

- · Other means of identification
- · Trade name: Essentia Light, Dark and Medium Dentin
- 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
- Details of the supplier of the safety data sheet Henry Schein Dental

243-249 Bush Road, Rosedale Auckland 0632, NEW ZEALAND

Free Phone: 0800 808 855

· Further information obtainable from: Regulatory affairs

· Emergency telephone number: 0800 764 766 (National Poisons Centre)

### 2 Hazards identification

· Classification of the substance or mixture

Acute oral toxicity Category 4 H302 Harmful if swallowed. Acute inhalation toxicity Category 3 H331 Toxic if inhaled.

Skin sensitisation Category 1 H317 May cause an allergic skin reaction.

Hazardous to the aquatic environment chronic Category 2H411 Toxic to aquatic life with long lasting effects.

- \_\_\_\_\_
- · Label elements
- · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · 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
- · Hazard-determining components of labelling:

Urethane Dimethacrylate (UDMA) Ytterbium trifluoride

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

· Hazard statements

Harmful if swallowed.

Toxic if inhaled.

May cause an allergic skin reaction.

Toxic to aquatic life with long lasting effects.

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#### · Precautionary statements

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

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

Wear protective gloves.

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

Store locked up.

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

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

### 3 Composition/Information on ingredients

- · 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 compone		25 - 500/
CAS: 72869-86-4	Urethane Dimethacrylate (UDMA)	25-<50%
EINECS: 276-957-5	Hazardous to the aquatic environment chronic Category 2, H411; Skin sensitisation Sub-category 1B, H317	
CAS: 1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate	5-<10%
EINECS: 217-856-8	Skin irritation Category 2, H315; Eye irritation Category 2, H319	
CAS: 13760-80-0	Ytterbium trifluoride	5-<10%
EINECS: 237-354-2	Acute oral toxicity Category 3, H301; Acute dermal toxicity Category 3, H311; Acute inhalation toxicity Category 3, H331	
CAS: 41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.	1-<2.5%
	Hazardous to the aquatic environment chronic Category 4, H413	
CAS: 9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde	0.5-<1%
	Serious eye damage Category 1, H318; Skin sensitisation Category 1, H317; Specific target organ toxicity - single exposure Category 3, H335	
CAS: 2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	0.1-<0.2%
EINECS: 219-470-5	Acute inhalation toxicity Category 3, H331; Skin sensitisation Category 1, H317	

<sup>·</sup> Additional information: For the wording of the listed hazard phrases refer to section 16.

### 4 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.

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· 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.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed Allergic reactions
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

### 5 Fire fighting measures

- · Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- · 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.

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

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

#### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Remove persons from danger area.

Avoid contact with the eyes and skin.

Wear protective clothing.

· 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.

· 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.

· 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

Ensure good ventilation/exhaustion at the workplace.

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

### 8 Exposure controls/personal protection

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

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

· Eye protection:



Tightly sealed goggles

### 9 Physical and chemical properties

- · General Information
- · Appearance:

· Form:

· Colour: According to product specification

**Odourless** 

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· Odour threshold: Not determined. · pH-value: Not determined.

· Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range: Undetermined.
 Flash point:
 Flammability
 Auto-ignition temperature:
 Decomposition temperature:
 Not determined.

• 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 determined.
Density: Not determined.
Relative density Not determined.
Vapour density Not determined.
Evaporation rate Not determined.

· Solubility in / Miscibility with

• water: Insoluble.
• Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined.
Kinematic: Not determined.

· Solvent content:

 $\cdot$  VOC (EC) 0.0 g/l

· Other information

• Particle characteristics SiO2: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-

based

Diameter agglomerate = 5 - 50 mm (laser diffraction dry module, d50,

volume based)

· Physical state Liquid

### 10 Stability and reactivity

- · Reactivity No further relevant information available.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

### 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity

Harmful if swallowed.

Toxic if inhaled.

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· LD/LC50 values relevant for classification:				
72869-86-	4 Urethane	e 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))		

- · Primary irritant effect:
- · 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 May cause an allergic skin reaction.
- · 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.
- · Interactive effects
- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
  No further relevant information available.

### 12 Ecological information

- · Toxicity
- · Aquatic toxicity:

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

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

- Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Ecotoxical 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

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

N7.

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### 13 Disposal considerations

- · 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.

UN-Number	UN2810
NZS, IMDG, IATA	UN2810
UN proper shipping name NZS	2010 TOVIC HOURD OPCANIC MOS (V44 amb):
NZS	2810 TOXIC LIQUID, ORGANIC, N.O.S. (Ytterbiv trifluoride), ENVIRONMENTALLY HAZARDOUS
IMDG	TOXIC LIQUID, ORGANIC, N.O.S. (Ytterbium trifluoria
	Urethane Dimethacrylate (UDMA)), MARINE POLLUTAN
IATA	TOXIC LIQUID, ORGANIC, N.O.S. (Ytterbium trifluoride,
Transport hazard class(es)	
NZS	
Class	6.1 (T1) Toxic substances.
Label	6.1
Class	6.1 Toxic substances.
Label	6.1
IATA	
Class	6.1 Toxic substances.
Label	6.1
Packing group	
NZS, IMDG, IATA	III
Environmental hazards:	Product contains environmentally hazardous substances: (2H-benzotriazol-2-yl)-p-cresol

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Marine pollutant:	No
•	Symbol (fish and tree)
Special marking (NZS):	Symbol (fish and tree)
Special precautions for user	Warning: Toxic substances.
Hazard identification number (Kemler code):	60
EMS Number:	F-A,S-A
Stowage Category	A
Stowage Code	SW2 Clear of living quarters.
Transport in bulk according to Annex II of Mar	pol
and the IBC Code	Not applicable.
Transport/Additional information:	
NZS	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
Transport category	2
Tunnel restriction code	E
<i>IMDG</i>	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	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
<u> </u>	TRIFLUORIDE), 6.1, III, ENVIRONMENTALL
	HAZARDOUS

### 15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· New Zealan	· New Zealand Inventory of Chemicals	
72869-86-4	Urethane Dimethacrylate (UDMA)	
68476-25-5	Feldspar-group minerals	
65997-17-3	Glass, oxide, chemicals	
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica	
1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate	
3290-92-4	Propylidynetrimethyl trimethacrylate	
13760-80-0	Ytterbium trifluoride	
41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.	
7128-64-5	2,5-Thiophendiylbis(5-tert-butyl-1,3-benzoxazol)	
9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde	
2530-85-0	3-trimethoxysilylpropyl methacrylate	
78-67-1	2,2'-dimethyl-2,2'-azodipropiononitrile	
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	

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	Camphorquinone	
21245-01-2	3-methylbutyl 4-(dimethylamino)benzoate	
1309-37-1	Iron(III)oxide	
	Iron (II,III) oxide	
13463-67-7	titanium dioxide	
20344-49-4	Iron hydroxide oxide	
1879-09-0	6-tert-butyl-2,4-xylenol	
128-37-0	Butylated hydroxytoluene	
· HSNO Approval numbers		

None of the ingredients is listed.

- GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Hazard pictograms





GHS06

- · Signal word Danger
- · Hazard-determining components of labelling:

*Urethane Dimethacrylate (UDMA)* 

Ytterbium trifluoride

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

· Hazard statements

Harmful if swallowed.

Toxic if inhaled.

May cause an allergic skin reaction.

Toxic to aquatic life with long lasting effects.

Precautionary statements

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

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

Wear protective gloves.

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

Store locked up.

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

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

### 16 Other information

· Relevant phrases

H301 Toxic if swallowed.

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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.

H411 Toxic to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

#### · 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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute oral toxicity Category 3: Acute toxicity - Category 3

Acute oral toxicity Category 4: Acute toxicity - Category 4

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

Serious eye damage Category 1: Serious eye damage/eye irritation – Category 1

Eye irritation Category 2: Serious eye damage/eye irritation – Category 2

Skin sensitisation Category 1: Skin sensitisation - Category 1

Skin sensitisation Sub-category 1B: Skin sensitisation – Category 1B

Specific target organ toxicity - single exposure Category 3: Specific target organ toxicity (single exposure) - Category 3

Hazardous to the aquatic environment chronic Category 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2

Hazardous to the aquatic environment chronic Category 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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