

Printing date 23.08.2023 Version number 5 Revision: 23.08.2023

1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: Essentia Red Brown, Black, White Modifier
- 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

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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

Aquatic Chronic 2 H411 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





GHS07

GHS09

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

Urethane Dimethacrylate (UDMA)

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

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.

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Avoid release to the environment.

Wear protective gloves / eye protection / face protection.

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

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 components:		
CAS: 72869-86-4	Urethane Dimethacrylate (UDMA)	50-<75%
EINECS: 276-957-5	Aquatic Chronic 2, H411; Skin Sens. 1, H317	
CAS: 1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate	10-<25%
EINECS: 217-856-8	Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 13463-67-7	titanium dioxide	1-<2.5%
EINECS: 236-675-5	Carc. 2, H351	
CAS: 21245-01-2	3-methylbutyl 4-(dimethylamino)benzoate	1-<2.5%
EINECS: 244-288-8	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	0.5-<1%
EINECS: 203-652-6	Skin Sens. 1, H317	
CAS: 1309-37-1	Iron(III)oxide	0.5-<1%
EINECS: 215-168-2		
CAS: 1879-09-0	6-tert-butyl-2,4-xylenol	0.5-<1%
EINECS: 217-533-1	Acute Tox. 2, H310; STOT RE 2, H373; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	0.5-<1%
EINECS: 219-470-5	Acute Tox. 3, H311; Acute Tox. 3, H331; Skin Sens. 1, H317	

[·] 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. 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:

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

If skin irritation continues, consult a doctor.

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· 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.

- · 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, 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
- · 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.

Do not allow to penetrate the ground/soil.

Do not allow to enter sewers/surface or ground water.

· Methods and material for containment and cleaning up:

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.

Prevent formation of aerosols.

Avoid contact with the eyes and skin.

• Information about fire - and explosion protection: No special measures required.

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- · 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

· Additional information about design of technical facilities: No further data; see section 7.

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

13463-67-7 titanium dioxide

WES (New Zealand) Long-term value: 10 mg/m³

1309-37-1 Iron(III)oxide

WES (New Zealand) Long-term value: 5 mg/m³ as Fe

· DNELs

13463-67-7 titanium dioxide

Inhalative DNEL inhalation 10 mg/m3 (man)

1879-09-0 6-tert-butyl-2,4-xylenol

Inhalative DNEL inhalation 0.14 mg/m3 (man)

- · 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:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Suitable respiratory protective device recommended.

· Protection of hands:

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.



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.

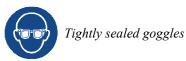
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Eye protection:



9 Physical and chemical properties

· General Information

· Appearance:

· Form: Pasty

• Colour: According to product specification

· Odour: Light

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

· Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range:
 Flash point:
 Flammability (solid, gas):
 Auto-ignition temperature:
 Decomposition temperature:
 Undetermined.
 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 at 20 °C: 1.9 g/cm³
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 No further relevant information available.

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.

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· Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

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

· LD/LC50 1	· LD/LC50 values relevant for classification:		
72869-86-	72869-86-4 Urethane Dimethacrylate (UDMA)		
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)	
13463-67-	13463-67-7 titanium dioxide		
Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)	
Inhalative	LC50/4 h	>6.82 mg/l (rat male)	
1309-37-1	1309-37-1 Iron(III)oxide		
Oral	LD50	>5,000 mg/kg (rat (f+m))	
1879-09-0	1879-09-0 6-tert-butyl-2,4-xylenol		
Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)	
Dermal	LD50	<200 mg/kg (rabbit) (OECD 402)	
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))	

- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye irritation.
- · 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.
- · Additional toxicological information:
- 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.

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- · Additional ecological information:
- · General notes:
- Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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 Transport inj	formation
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· UN-Number · NZS, IMDG, IATA	UN3082
· UN proper shipping name · NZS	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA), 6-tert-butyl-2,4-xylenol)
· IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA), 6-tert- butyl-2,4-xylenol), MARINE POLLUTANT
· IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA), 6-tert-butyl-2,4-xylenol)

- · Transport hazard class(es)
- · NZS



• Class 9 (M6) Miscellaneous dangerous substances and articles. • Label 9

· IMDG, IATA



Class
 Label
 9 Miscellaneous dangerous substances and articles.
 9

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	(Contd. of page
Packing group NZS, IMDG, IATA	III
Environmental hazards:	
Marine pollutant:	No
	Symbol (fish and tree)
Special marking (NZS):	Symbol (fish and tree)
Special marking (IATA):	Symbol (fish and tree)
Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
Hazard identification number (Kemler code):	90
EMS Number:	F- A , S - F
Stowage Category	A
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	3
Tunnel restriction code	(-)
<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 3082 ENVIRONMENTALLY HAZARDOU
0	SUBSTANCE, LIQUID, N.O.S. (URETHAN
	DIMETHACRYLATE (UDMA), 6-TERT-BUTYL-2,4
	XYLENOL), 9, III

15 Regulatory information

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

· New Zealar	nd Inventory of Chemicals
72869-86-4	Urethane Dimethacrylate (UDMA)
1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica
10373-78-1	Camphorquinone
13463-67-7	titanium dioxide
21245-01-2	3-methylbutyl 4-(dimethylamino)benzoate
81-77-6	C.I. Pigment Blue 60
	2,2'-ethylenedioxydiethyl dimethacrylate
1309-37-1	Iron(III)oxide
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1317-61-9	triiron tetraoxide	
1879-09-0	6-tert-butyl-2,4-xylenol	
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	
5280-78-4	CI Pigment Red 144	
5580-57-4	C.I. Pigment Yellow 93	
HCNO Ann	HCNO Annuoud www.hore	

· HSNO Approval numbers

1879-09-0 6-tert-butyl-2,4-xylenol

HSR003625

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





GHS07 (

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

Urethane Dimethacrylate (UDMA)

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

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.

Avoid release to the environment.

Wear protective gloves / eye protection / face protection.

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

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 E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

· Relevant phrases

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

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H351 Suspected of causing cancer.

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

H411 Toxic to aquatic life with long lasting effects.

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- · Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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)

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

Acute Tox. 4: Acute toxicity - Category 4

Acute Tox. 2: Acute toxicity - Category 2

Acute Tox. 3: Acute toxicity - Category 3

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

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

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 2: Carcinogenicity – Category 2

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

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

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

· 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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