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

Printing date 23.08.2023

Version number 5 (replaces version 4)

Revision: 23.08.2023

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

· 1.1 Product identifier

· Trade name:

Essentia_Red-Brown,_Black,_White_Modifier

Nanoform

- 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 Auxiliary 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

· Information department: Regulatory affairs

· 1.4 Emergency telephone number: International: +01-813-248-0585 (ChemTel Inc.)

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

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

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.

· 2.2 Label elements

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

The product is classified and labeled according to the 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



· Signal word Warning

• Hazard-determining components of labeling: Urethane Dimethacrylate (UDMA) 2,2'-ethylenedioxydiethyl dimethacrylate 2-(2H-benzotriazol-2-yl)-p-cresol

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lazard statements	
315 Causes skin irritation.	
319 Causes serious eye irritation.	
317 May cause an allergic skin reaction.	
1411 Toxic to aquatic life with long lasting effects.	
recautionary statements	
261 Avoid breathing dust/fume/gas/mist/vapors/spray	
272 Contaminated work clothing must not be allowed out of the workplace.	
273 Avoid release to the environment.	
280 Wear protective gloves / eye protection / face protection.	
305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, and easy to do. Continue rinsing.	if present
501 Dispose of contents/container in accordance with local/regional/national/inte regulations.	rnational
dditional information:	
% of the mixture consists of component(s) of unknown toxicity.	
ontains 2 % of components with unknown hazards to the aquatic environment.	
3 Other hazards	
esults of PBT and vPvB assessment	

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterization: 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.

0	components:	50-<75%
	Urethane Dimethacrylate (UDMA)	50-<75%
	Aquatic Chronic 2, H411; Skin Sens. 1B, H317	10
	2,2-dimethyl-1,3-propanediyl bismethacrylate	10-<25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319	
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica	10-<25%
13463-67-7	titanium dioxide	1-<2.5%
	Carc. 2, H351	
21245-01-2	3-methylbutyl 4-(dimethylamino)benzoate	1-<2.5%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	0.5-<1%
	Skin Sens. 1, H317	
1879-09-0	6-tert-butyl-2,4-xylenol	0.5-<1%
	<i>Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319</i>	
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	0.5-<1%
	Acute Tox. 3, H331; Aquatic Chronic 1, H410; Skin Sens. 1, H317	

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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. 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:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.

- 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 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. Do not allow to enter sewers/ surface or ground water.
6.3 Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material.

Dispose of the collected material according to regulations.

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· 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 protection against explosions and fires: No special measures required.

· 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

• Components 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.

· 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 that were valid during the creation were used as basis.

· 8.2 Exposure controls

• Additional information about design of technical systems: No further data; see section 7.

- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed. Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing.

• Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air. Suitable respiratory protective device recommended.

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• 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.

• Eye protection:



*

Tightly sealed goggles

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemica General Information	n properties	
Physical state	Fluid	
Color:	According to product specification	
Odor:	Light	
Odor threshold:	Not determined.	
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined	
Flammability (solid, gaseous):	Not applicable.	
Explosion limits:	11	
Lower:	Not determined.	
Upper:	Not determined.	
Flash point:	Not applicable.	
Auto igniting:	Undetermined.	
Decomposition temperature:	Not determined.	
pH-value:	Not determined.	
Viscosity:		
Kinematic:	Not determined.	
Dynamic:	Not determined.	
Solubility in / Miscibility with		
Water:	Insoluble.	
Partition coefficient (n-octanol/water):	Not determined.	
Vapor pressure:	Not determined.	
Density and/or relative density		
Density at 20 °C:	$1.9 \ g/cm^3$	
Relative density	Not determined.	

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Vapor density	Not determined.
Particle characteristics	SiO2: Diameter particle structure = $2.5 - 50$ nm (TEN
	d50, number-based)
	Diameter agglomerate = $5 - 50$ mm (laser diffraction di
	module, d50, volume based)
	68611-44-9 Silane, dichlorodimethyl-, reaction produc
	with silica: Spheroidal, amorphous nanoform, s
	including amorphous nanoforms, amorphous form
	surface-treated nanoforms
9.2 Other information	
Appearance:	
Form:	Pasty
Important information on protection of healt	th and
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Solvent content:	0.0 //
VOC (EC)	$0.0 \ g/l$
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard class	
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 Void
Pyrophoric liquids	Void Void
Pyrophoric solids	Void
Self-heating substances and mixtures Substances and mixtures, which emit flammable	
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.

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· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

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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 that are relevant for classification:

72869-86-4 Urethane Dimethacrylate (UDMA)

Oral LD50 >5,000 mg/kg (rat female) (OECD 401)

13463-67-7 titanium dioxide

Oral LD50 >5,000 mg/kg (mouse) (*OECD* 420)

Inhalative |LC50/4|h| > 6.82 mg/l (rat male)

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))

• on the skin: Causes skin irritation.

• on the eye: Causes serious eye irritation.

• Sensitization: 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.

• Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

• Specific target organ toxicity - 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:

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

• *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 disrupting properties

None of the ingredients is listed.

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)

• 12.2 Persistence and degradability No further relevant information available.

• 12.3 Bioaccumulative potential No further relevant information available.

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- 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 (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 of together with household garbage. Do not allow product to reach sewage system.

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

- 14.1 UN-Number - ADR, IMDG, IATA	UN3082
14.2 UN proper shipping name	
DOT	not regulated
ADR	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA), 6-terr butyl-2,4-xylenol)
·IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUIE N.O.S. (Urethane Dimethacrylate (UDMA), 6-tert-butyl-2,4 xylenol), MARINE POLLUTANT
IATA	ÉNVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUIL N.O.S. (Urethane Dimethacrylate (UDMA), 6-tert-butyl-2,4 xylenol)
14.3 Transport hazard class(es)	
ADR	
- Class	9 (M6) Miscellaneous dangerous substances and articles
· Lahel	9

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IMDG, IATA	
Class	9 Miscellaneous dangerous substances and articles
Label	9
14.4 Packing group ADR, IMDG, IATA	111
14.5 Environmental hazards: Marine pollutant:	No Symbol (fish and tree)
Special marking (ADR): Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree)
14.6 Special precautions for user Hazard identification number (Kemler code): EMS Number: Stowage Category	Warning: Miscellaneous dangerous substances and articles 90 F-A,S-F A
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	o f Not applicable.
Transport/Additional information:	
ADR 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
Transport category Tunnel restriction code	3 (-)
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 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCH LIQUID, N.O.S. (URETHANE DIMETHACRYLATE (UDMA) 6-TERT-BUTYL-2,4-XYLENOL), 9, III

SECTION 15: Regulatory information

 \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture \cdot Sara

• Section 355 (extremely hazardous substances):

None of the ingredient is listed.

• Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

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Proposition		ntd. of page
-	known to cause cancer:	
	titanium dioxide	
	known to cause reproductive toxicity for females:	
	ingredients is listed.	
,	known to cause reproductive toxicity for males:	
	ingredients is listed.	
v	-	
	anown to cause developmental toxicity: ingredients is listed.	
	• •	
-	ic categories	
	onmental Protection Agency)	
v	ingredients is listed.	
	hold Limit Value)	
	titanium dioxide	A
1309-37-1	Iron(III)oxide	A
,	aan Maximum Workplace Concentration)	
13463-67-7	titanium dioxide	3
NIOSH-Ca	(National Institute for Occupational Safety and Health)	
13463-67-7	titanium dioxide	
Seveso cate Qualifying Qualifying	12/18/EU gerous substances - ANNEX I None of the ingredients is listed. gory E2 Hazardous to the Aquatic Environment quantity (tonnes) for the application of lower-tier requirements 200 t quantity (tonnes) for the application of upper-tier requirements 500 t ION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3	
	E 2011/65/EU on the restriction of the use of certain hazardous substances in elec quipment – Annex II	ctrical a
•	ingredients is listed.	
	ION (EU) 2019/1148	
Article 5(3)		ising un
None of the	ingredients is listed.	
Annex II - I	REPORTABLE EXPLOSIVES PRECURSORS	
None of the	ingredients is listed.	
Regulation	(EC) No 273/2004 on drug precursors	
None of the	ingredients is listed.	
	(EC) No 111/2005 laying down rules for the monitoring of trade between the Communit drug precursors	y and th
	ingredients is listed.	

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SECTION 16: Other information	
Relevant phrases	
H302 Harmful if swallowed.	
H302 Harmjul if swallowed. H310 Fatal 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.	
H351 Suspected of causing cancer.	
H373 May cause damage to organs through prolonged or repeated exp	posure.
H410 Very toxic to aquatic life with long lasting effects.	
H411 Toxic to aquatic life with long lasting effects.	
Classification according to Regulation (EC) No 1272/2008 Calculation	on method
	n nenou
Department issuing SDS: Regulatory affairs Contact: msds@gc.dental	
Date of previous version 23.08.2023	
Version number of previous version: 4	
Abbreviations and acronyms:	
Aboreviations and acronyms: RID: Règlement international concernant le transport des marchandises dangereu.	ses new chamin de feu (Paquilations Concerning
International Transport of Dangerous Goods by Rail)	ses par chemin de jer (Regulations Concerning
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Associa	ution" (IATA)
ICAO: International Civil Aviation Organisation	
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (IC	CAO)
ADR: Accord relatif au transport international des marchandises dangereuses par rout	te (European Agreement Concerning the Internation
Carriage of Dangerous Goods by Road)	
IMDG: International Maritime Code for Dangerous Goods	
DOT: US Department of Transportation 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 (REACH)	
LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent	
PBT: Persistent, Bioaccumulative and Toxic	
vPvB: very Persistent and very Bioaccumulative	
NIOSH: National Institute for Occupational Safety	
OSHA: Occupational Safety & Health	
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: Skin corrosion/irritation – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2	
Skin Sens. 1: Skin sensitisation – Category 1	
Skin Sens. 12: Skin sensitisation – Category 1 Skin Sens. 1B: Skin sensitisation – Category 1B	
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 1: Hazardous to the aquatic environment - long-term aquatic hazard -	
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard -	- Category 2
Sources	
• ECHA (http://echa.europa.eu/)	
• EnviChem (www.echemportal.org)	
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• * Data compared to the previous version altered.

This version replaces all previous versions.

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