

Printing date 03.08.2018 Version number 3 Revision: 08.02.2017

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

- · 1.1 Product identifier
- · Trade name: everX Posterior
- 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 Dam. 1 H318 Causes serious eye damage.

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





GHS05

GHS07

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

 $(1-methylethylidene) bis [4,1-phenylene oxy(2-hydroxy-3,1-propane diyl)]\ bismethac rylate 2,2'-ethylene dioxydiethyl dimethac rylate$

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· Hazard statements

H318 Causes serious eye damage.

H317 May cause an allergic skin reaction.

· Precautionary statements

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

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: 1565-94-2 EINECS: 216-367-7	(1-methylethylidene)bis $[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]$ bismethacrylate	10-<25%
	Eye Dam. 1, H318; Skin Sens. 1, H317	
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	5-<10%
CAS: 75980-60-8 EINECS: 278-355-8 Index number: 015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	0.1-<0.2%
CAS: 1879-09-0 EINECS: 217-533-1	6-tert-butyl-2,4-xylenol Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	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. Take affected persons into fresh air and keep quiet.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

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If skin irritation continues, consult a doctor.

· After eye contact:

Protect unharmed eye.

Rinse opened eye for several minutes under running water.

Call a doctor immediately.

· 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, 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.

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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:

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

· DNELs

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.
- · 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.

Keep away from foodstuffs, beverages and feed.

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.

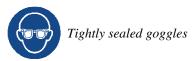
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· Eye protection:



SECTION 9: Physical and chemical properties · 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Solid

Colour: According to product specification

· Odour: Characteristic · 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.

Undetermined. · Ignition temperature:

· 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.

Not determined. · Density: Not determined. · Relative density · Vapour density Not applicable.

Not applicable. · Evaporation rate

· Solubility in / Miscibility with

water: Insoluble.

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

· Viscosity:

Dynamic: Not applicable. Not applicable. Kinematic:

· Solvent content:

0.0 % Organic solvents:

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· 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 value	s relevant for	classification:
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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)</td>

- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation

Causes serious eye damage.

· Respiratory or skin sensitisation

May cause an allergic skin reaction.

- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, 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: No further relevant information available.
- · 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.
- · 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.

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- · 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	
	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 dangerous substances

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

SECTION 14	: Transport information

not regulated	
not regulated	
not regulated	
not regulated	
No	
Not applicable.	
Transport in bulk according to Annex II of Not applicable.	
not regulated	

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.

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

SECTION 16: Other information

· Relevant phrases

H302 Harmful if swallowed.

H310 Fatal 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.

H361f Suspected of damaging fertility.

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

H411 Toxic to aquatic life with long lasting effects.

· 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

Acute Tox. 4: Acute toxicity - Category 4

Acute Tox. 2: Acute toxicity – Category 2

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

Repr. 2: Reproductive toxicity – Category 2

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

 $A quatic\ Chronic\ 2:\ Hazardous\ to\ the\ aquatic\ environment\ -\ long\ -term\ aquatic\ hazard\ -\ Category\ 2$

· 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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