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Safety Data Sheet in accordance with HSNO

Printing date 05.06.2023

Version number 3

Revision: 05.06.2023

1 Identification of the substance or mixture and of the supplier

- · Product identifier
- Trade name: everX Posterior

• *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 Sens. 1 H317 May cause an allergic skin reaction.

Repr. 2 H361 Suspected of damaging fertility or the unborn child.

· 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



· Signal word Warning

Hazard-determining components of labelling: 2,2'-ethylenedioxydiethyl dimethacrylate diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
Hazard statements May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child.
Precautionary statements Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. IF exposed or concerned: Get medical advice/attention. Specific treatment (see on this label). Take off contaminated clothing and wash it before reuse. Store locked up.

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(Contd. of page 1) 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: 109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	5-<10%
EINECS: 203-652-6	Skin Sens. 1, H317	
CAS: 1879-09-0	6-tert-butyl-2,4-xylenol	0.1-<0.2%
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: 75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	0.1-<0.2%
EINECS: 278-355-8	•	
• 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.

• After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, 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, sand, extinguishing powder. Do not use water. • For safety reasons unsuitable extinguishing agents: Water

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• 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
	versons from danger area.
Avoid for	rmation of dust.
Avoid co	ntact with the eyes and skin.
Wear pro	ptective clothing.
Environ	mental precautions:
Do not a	llow product to reach sewage system or any water course.
Inform re	espective authorities in case of seepage into water course or sewage system.
	llow to penetrate the ground/soil.
In case o	f seepage into the ground inform responsible authorities.
Methods	and material for containment and cleaning up:
Pick up r	nechanically.
Prevent	formation of dust.
Dispose	of the material collected according to regulations.
Referenc	e to other sections
See Secti	on 7 for information on safe handling.
See Secti	on 8 for information on personal protection equipment.
See Secti	on 13 for disposal information.
	· · ·

7 Handling and storage

• Handling:

· Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. 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: Protect against electrostatic charges.

Dust can combine with air to form an explosive mixture.

· 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.

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· 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.

- · 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.

• Eye protection:



Tightly sealed goggles

Solid	
According to product specification	
Characteristic	
Not determined.	
Not applicable.	
Undetermined.	
ge: Undetermined.	
Not applicable.	
Not determined.	
Undetermined.	
Undetermined.	(Contd. on
	According to product specification Characteristic Not determined. Not applicable. Undetermined. ge: Undetermined. Not applicable. Not determined. Not determined.

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· 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 applicable.	
Density:	Not determined.	
· Relative density	Not determined.	
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
Solubility in / Miscibility with	•••	
water:	Insoluble.	
• Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
· Dynamic:	Not applicable.	
· Kinematic:	Not applicable.	
• 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.
- · 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 values relevant for classification:

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)

• 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 Suspected of damaging fertility or the unborn child.*

• 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.*

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· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

12 Ecological information

· Toxicity

- · Aquatic toxicity: No further relevant information available.
- 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.
- 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.

- · 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 information

· UN-Number · NZS, ADN, IMDG, IATA	not regulated	
	noireguiaica	
· UN proper shipping name · NZS, ADN, IMDG, IATA	not regulated	
· Transport hazard class(es)		
· NZS, ADN, IMDG, IATA		
· Class	not regulated	
· Packing group · NZS, IMDG, IATA	not regulated	
Environmental hazards: Marine pollutant:	No	
Special precautions for user	Not applicable.	
· Transport in bulk according to Annex I	I of Marpol	
and the IBC Code	Not applicable.	
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not regulated

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HSR003625

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· UN "Model Regulation":

15 Regulatory information

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

· New Zealand Inventory	of	Chemicals
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1565-94-2	1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	

65997-17-3 Glass, oxide, chemicals

109-16-0 2,2'-ethylenedioxydiethyl dimethacrylate

2530-85-0 3-trimethoxysilylpropyl methacrylate

112945-52-5 Silicon dioxide 1879-09-0 6-tert-butyl-2,4-xylenol

9011-14-7 Polymethylmethacrylate

10287-53-3 ethyl 4-dimethylaminobenzoate

10373-78-1 Camphorquinone

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol

· HSNO Approval numbers

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

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



· Signal word Warning

• *Hazard-determining components of labelling:* 2,2'-ethylenedioxydiethyl dimethacrylate diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· Hazard statements

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. *IF exposed or concerned: Get medical advice/attention.*

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

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.

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

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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. H319 Causes serious eye irritation. H361 Suspected of damaging fertility or the unborn child. H373 May cause damage to organs through prolonged or repeated exposure. · 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) 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 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

Sources

• ECHA (http://echa.europa.eu/)

• EnviChem (www.echemportal.org)

• * Data compared to the previous version altered.

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