

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

1.1 Product identifier

Product name : E-Denture, E-Dent 400, E-Guide Tint

Product description : Monomer based on acrylic esters

Alternative names : E-Denture, E-Dent 400, E-Guide Tint

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use : E-Denture: Monomer based on acrylic esters for manufacturing of 3D-printed denture bases.
E-Dent 400: Monomer based on acrylic esters for manufacturing of 3D-printed crowns and bridges based on acrylic esters.
E-Guide Tint: Monomer based on acrylic esters for manufacturing of 3D-printed surgical guides.

Uses advised against : Mixtures containing unreacted liquid monomer intended to come into contact with skin or nails.

Refer to Exposure Scenario Annex for further details.

1.3 Details of the supplier of the safety data sheet

Address/Phone no. : Vertex-Dental B.V.
PO Box 10
3700 AA Zeist The Netherlands
info@vertex-dental.com
www.vertex-dental.com

Emergency Phone No. : +31 88 616 04 40 (only available during office hours)

Local Contact Details : EnvisionTEC GmbH
Brüsseler Straße 51
D-45968 Gladbeck, Germany
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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

According to Regulation (EG) No. 1272/2008 [CLP].	Skin sens.	Cat. 1	H317
	Aquatic Chronic	Cat. 4	H413

For full text of H phrases see section 16.

2.2. Label elements

Pictogram



Signal word : Warning

Hazard statements : H317 : May cause an allergic skin reaction.
H413 : May cause long-lasting harmful effects to aquatic life.

Precautionary statements	P280 P261 P272 P273 P302+P352 P305+P351+P338 P333+P313 P362+P364 P501	Wear protective gloves/protective clothing/eye protection/face protection. Avoid breathing dust/fumes/gas/mist/vapours/spray. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. IF ON SKIN: Wash with plenty of soap and water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. If skin irritation or a rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Dispose of contents/container in accordance with local/regional/national/ international regulation.
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2.3. Other hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Substances in the product which may present a health or environmental hazard, or which have been assigned occupational exposure limits, are detailed below.

According to Regulation (EG) Nr. 1272/2008 [CLP].

HAZARDOUS INGREDIENT(S)	% w/w	EG No.	Hazard Class and Category Code(s)	Hazard statement Code(s)
Ethoxylated Bisphenol A	> 60	609-946-4	Aquatic Chronic Cat 4	H413
Methacrylic oligomer	15 - 25	Proprietary	Skin sens. Cat 1	H317
Phosphine oxide	< 2,5	423-340-5	Skin sens Cat 1 Aquatic Chronic Cat 4	H317 H413

For full text of H phrases see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Move into fresh air and keep at rest. Get medical attention if any discomfort continues.
Skin Contact	Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention promptly if irritation or other symptoms occur after washing.
Eye Contact	Continue to rinse for at least 15 minutes under running water with eyelids held open. Get medical attention if any discomfort continues.
Ingestion	Do not induce vomiting. Immediately rinse mouth and drink plenty of water. Get medical attention if any discomfort continues

4.2. Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11. Further important symptoms and effects are so far not known.

4.3. Indication of the immediate medical attention and special treatment needed

Note to physician.

Treatment Treat according to symptoms (decontamination, vital functions), no known specific antidote.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Water spray, dry powder, CO₂.

Unsuitable Extinguishing Media Water jet.

5.2. Special hazards arising from the substance or mixture

Hazards during fire-fighting Harmful vapours.
Evolution of fumes/fog.

Unsuitable Extinguishing Media Water jet.

High temperatures may cause spontaneous polymerizing reaction generating heat/pressure. Closed containers may rupture or explode during a runaway polymerization. Use a water spray or fog to reduce temperature of containers.

5.3. Advice for fire-fighters

Protective equipment Wear a self-contained breathing apparatus and full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use protective gloves, goggles and suitable protective clothing. In case of inadequate ventilation, use respiratory protection. Maximize ventilation after accidental release.

6.2. Environmental precautions

Contain contaminated water / firefighting water. Do not discharge into drains/surface waters/groundwater. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Remove sources of ignition. Absorb with sand or other inert absorbent. Spillage may be stored as chemical waste in approved area.

6.4. Reference to other sections

See section 8, 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Keep away from heat, sparks and open flame. Use mechanical ventilation in case of handling which causes formation of vapours. Handle and open container with care. Wear full protective clothing for prolonged exposure and/or high concentrations. Take precautionary measures against static discharges.

7.2. Conditions for safe storage, including any incompatibilities

Protect from light, including direct sunrays. Container may be filled for only 90%. Keep containers tightly closed, separate from oxidizing agents. Store in original container in a dry, cool and well-ventilated place. Store at temperatures below 30°C. High temperatures may cause spontaneous polymerization.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Substance	EG No.
Ethoxylated Bisphenol A (100%)	609-946-4

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	¹	3,52 mg/m ³	2 mg/kg

PNEC (100% component)	
Aquatic Compartment	Not applicable
Terrestrial Compartment	Not applicable

¹ Toxicity: DNEL not established.

Substance	EG No.
Methacrylic oligomer (100%)	Proprietary

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	¹	¹	¹

PNEC (100% component)	
Aquatic Compartment	Not applicable
Terrestrial Compartment	Not applicable

¹ Toxicity: DNEL not established.

Substance	EG No.
Phosphine oxide (100%)	423-340-5

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	¹	21 mg/m ³	3,3 mg/kg

PNEC (100% component)	
Aquatic Compartment	Not applicable
Terrestrial Compartment	Not applicable

¹ Toxicity: DNEL not established.

8.2. Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the work place. Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection	Wear eye/face protection. Wear approved chemical safety goggles where eyes exposure must be provided.
Skin protection	Wear suitable gloves. Butyl and nitrile rubber gloves offer short-term protection. Gloves should be stored correctly and changed regularly, especially if excessive exposure has occurred.
Respiratory protection	Wear suitable respiratory protective equipment if engineering controls are insufficient, or not present, and exposure to levels above the DNEL is likely. A suitable mask with filter type P2 may be appropriate.
Other	Keep working clothes separately. Take off contaminated clothing immediately. Wash soiled clothing before reuse. Keep away from food, drinks and animal feed. Wash hands thoroughly after handling.

Environmental exposure controls

Ensure effective control measures when working within the boundaries as specified in section 6.2 of each GES.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance 'E-Denture'	Pink
Appearance 'E-Dent 400'	Tooth coloured
Appearance 'EGuide Tint'	Translucent Orange
Odour	Ester like
pH	Not applicable
Melting point	Not applicable
Boiling point	> 200°C
Flash point	Not applicable
Flammable limits (lower) (%v/v)	Not applicable
Auto ignition temperature	375°C
Explosive properties	Not applicable
Oxidizing properties	Not applicable
Oxidizing properties	Not applicable
Vapour pressure	-
Relative density	1.1-1.2 (water = 1)
Solubility	Good solubility with most organic solvents
Water solubility	Not soluble
Viscosity	1.1 - 1.6 Pa • s

9.2. Other information

None.

SECTION 10: Stability and reactivity

10.1. Reactivity

See part 10.2.

10.2. Chemical stability

Stable under normal temperature conditions. Stable if stored and handles as prescribed/indicated.

10.3. Possibility of hazardous reactions

Hazardous polymerization. May polymerize.

10.4. Conditions to avoid

Avoid heat, flames and other sources of ignition. Avoid contact with free radical initiators. Avoid contact with isocyanates and oxidizing agents. Avoid contact with vinyl polymerization initiators. Avoid exposure to high temperatures, direct sunlight or ultra violet (UV) radiation.

10.5. Incompatible materials

Avoid contact with radical forming initiators, peroxides, strong alkalis or reactive metals to prevent exothermic polymerization.

10.6. Hazardous Decomposition Product(s)

With regard to possible decomposition products refer to Section 5. Oxides of carbon

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Stable Acute toxicity:

Ethoxylated Bisphenol A (100%)

LD50 acute oral rat	> 2000 mg/kg
LD50 acute dermal rat	> 2000 mg/kg
Skin irritation (rabbit, OECD 404)	Non-irritant
Eye irritation (rabbit, OECD 405)	Non-irritant
Skin sensitisation (mouse, OESO 429, LLNA)	No sensitisation
Aspiration Hazard	No aspiration hazard expected

Methacrylic oligomer (100%)

Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitisation	May cause sensitisation by skin contact.
Aspiration Hazard	Not applicable

Phosphine oxide (100%)

LD50 acute oral rat	> 2000 mg/kg
LD50 acute dermal rat	> 2000 mg/kg
Skin irritation (rabbit, 24 h, Draize)	Non-irritant
Eye irritation (rabbit, Draize)	Non-irritant
Skin sensitisation guinea pig (GPMT)	Sensitizing
Aspiration Hazard	Not relevant
Reproductive toxicity (animal studies)	NOAEL: > 1000 mg/kg/day, Oral, Rat

SECTION 12: Ecological information

12.1. Toxicity

Ethoxylated Bisphenol A (100%)

Toxicity to fish (mg/l)	LL50 (96h) (Oncorhynchus mykiss) (OECD 203)	> 100
Aquatic invertebrates (mg/l)	EL50 (72 h) (Daphnia magna) (OECD 202)	> 100

Aquatic plants (mg/l)	EL50 (72 h) (Pseudokirchneriella subcapitata) (OECD 201)	> 100
	NOEC (72 h) (Selenastrum capricornutum) (OESO 201)	> 100
Micro-organisms (mg/l)	NOEC (28 d) (Activated sludge) (DEV L8)	14,3

Methacrylic oligomer (100%)

No data available.

Phosphine oxide (100%)

Toxicity to fish (µg/l)	LC50 (96 h) (Brachydanio rerio) (OESO 203)	> 90
Aquatic invertebrates (µg/l)	EC50 (48 h) (Daphnia magna) (OECD 202)	> 1175
Aquatic plants (µg/l)	EC50 (72 h) (Desmodesmus subspicatus) (OECD 201)	> 260
Micro-organisms (mg/l)	EC50 (3 h) (Activated sludge) (DEV L8)	> 100

12.2. Persistence and degradability

Ethoxylated Bisphenol A (100%)

Poorly biodegradable.

24% after 28 d (OESO 301D)

54% after 63 d (OESO 301D)

Methacrylic oligomer (100%)

No data available.

Phosphine oxide (100%)

Poorly biodegradable. Not readily biodegradable (by OECD criteria).

Elimination information:

1 % CO₂ BOD of the ThOD (29 d) (OECD 301 B) (activated sludge)

12.3. Bioaccumulative potential

Ethoxylated Bisphenol A (100%)

Possible bioaccumulative.

Methacrylic oligomer (100%)

No data available.

Phosphine oxide (100%)

Does not significantly accumulate in organisms.

Bioaccumulative potential: BCF <5, Cyprinus carpio (Common carp).

12.4. Mobility in soil

Ethoxylated Bisphenol A

Soluble in water. Adsorption: Water - Log Koc: 3,88.

Methacrylic oligomer (100%)

No data available.

Phosphine oxide (100%)

Insoluble in water. Adsorption: Water – Log Koc: 3.85 @ 40°C.

12.5. Results of PBT and vPvB assessment

Ethoxylated Bisphenol A (100%)

PBT: no

vPvB: no

Methacrylic oligomer (100%)

PBT: no

vPvB: no

Phosphine oxide (100%)

PBT: no

vPvB: no

12.6. Other adverse effects

Ethoxylated Bisphenol A (100%)

Not applicable.

Methacrylic oligomer (100%)

Not applicable.

Phosphine oxide (100%)

Not applicable.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not discharge into drains/surface waters/groundwater. Dispose of in accordance with national, state and local regulations. Incinerate under approved controlled conditions, using incinerators for the disposal for organic chemicals. Decontaminate empty drums before recycling.

SECTION 14: Transport information

14.1. UN-Nummer

Not classified as a dangerous good under transport regulations.

14.2. UN Proper Shipping Name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Toxic to aquatic life with long lasting effects.

14.6. Special precautions for user

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14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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SECTION 15: Regulatory information

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

If information other than the information in relation to safety, health and environmental regulations / legislation what is mentioned elsewhere in this Safety Data Sheet is required, please use the information listed in Section 1 to inquire whether that specific information is available. Related information about the separate components in the mixture can be accessed the same way.

15.2. Chemical Safety Assessment

A Chemical Safety Assessment has been carried out for the following individual components (100%): Ethoxylated Bisphenol A and Phosphine oxide.

SECTION 16: Other information

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) No. 453/2010.

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process unless specified in the text.

Legend

Note: Not all of the following are necessarily contained in this Safety Data Sheet:

IOELV	Indicative Occupational Exposure Limit Value.
WEL	Workplace Exposure Limit.
Bmgv	Biological Monitoring Guidance Value.
Sen.	Capable of causing respiratory sensitization.
Sk	Can be absorbed through skin.
Carc	Capable of causing cancer and/or heritable genetic damage.
CHAN	Chemical Hazard Alert Notice.
COM	The company aims to control exposure in its workplace to this limit.
LTEL	Long Term Exposure Limit.
STEL	Short Term Exposure Limit.
TWA	Time Weighted Average.
STOT SE	Specific Target Organ Toxicity – Single Exposure.
Repr.	Reproductive toxicity.
Aquatic acute/chronic	Hazardous to the aquatic environment.

Full text of H/P phrases

H317	May cause an allergic skin reaction.
H413	May cause long-lasting harmful effects to aquatic life.
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention
P362 + P364	Take off contaminated clothing and wash it before reuse.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.

This is the end of SDS ID: SENP2201701UK

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