

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

### 1.1 Product identifier

**Product name** : NextDent™ Ortho Clear

**Product description** : Monomer based on acrylic esters

**Alternative names** : Ortho Clear

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

**Identified use** : Monomer based on acrylic esters for manufacturing of 3D-printed splints and retainers.

**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](mailto:info@vertex-dental.com)  
[www.vertex-dental.com](http://www.vertex-dental.com)

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

**Local Contact Details** :

**Local Emergency Phone No.** :

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

According to Regulation (EG) No. 1272/2008 [CLP].	Skin irrit.	Cat. 2	H315
	Skin sens.	Cat. 1	H317
	Eye irrit.	Cat. 2	H319
	Aquatic chronic.	Cat. 2	H411

For full text of H phrases see section 16.

### 2.2. Label elements

**Pictogram**



**Signal word**

Warning

<b>Hazard statements</b>	H315 H317 H319 H411	Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. Toxic to aquatic life with long-lasting effects.
<b>Precautionary statements</b>	P280 P261 P264 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. Wash hands and exposed skin thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. 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.

### 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	EINECS No.	Hazard Class and Category Code(s)	Hazard statement Code(s)
Methacrylic oligomer	> 70	Proprietary	Skin irrit. Cat 2 Skin Sens. Cat 1 Eye irrit. Cat 2	H315 H317 H319
Glycol Methacrylate	< 20	Proprietary	Skin sens. Cat 1 Eye irrit. Cat 2	H317 H319
Pentamethyl-piperidyl sebacate	< 5	255-437-1	Skin sens. Cat 1 Aquatic acute Cat 1 Aquatic chronic Cat 1	H317 H400 H410
Phosphine oxide	< 2,5	278-355-8	Skin sens. Cat 1 Repr. Cat 2 Aquatic acute Cat 2 Aquatic chronic Cat 2	H317 H361 H401 H411

For full text of H phrases see section 16.

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## SECTION 4: First aid measures

### 4.1. Description of first aid measures

Inhalation	IF INHALED: Move into fresh air and keep at rest. Get medical attention if any discomfort continues.
Skin Contact	IF ON SKIN (or hair): 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	IF IN EYES: Continue to rinse for at least 15 minutes under running water with eyelids held open. Get medical attention.
Ingestion	Do not induce vomiting. Never induce vomiting or give anything by mouth if the victim is unconscious or having convulsions. Immediately rinse mouth and drink plenty of water. Keep person under observation. If person becomes uncomfortable get medical attention.

### 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.
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## SECTION 5: Fire-fighting measures

### 5.1. Extinguishing media

Suitable Extinguishing Media Water spray, dry powder, CO<sub>2</sub>.

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.

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.

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## 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 between 5°C and 30°C. Do not expose to temperatures above 50°C for more than 24 hours. 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.
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

<sup>1</sup> Toxicity: DNEL not established.

Substance	EG No.	LTEL ppm (8 Hr TWA)	LTEL mg/m <sup>3</sup> (8 h TWA)
Glycol Methacrylate (100%)	Proprietary	0,05	0,24

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	1	4,9 mg/m <sup>3</sup>	1,3 mg/kg/d

PNEC (100% component)	
Aquatic Compartment	10 mg/l (Fresh water) 0,482 mg/l (Sea water) 3,79 mg/kg dry weight (Sediment)
Terrestrial Compartment	0,476 mg/kg dry weight

<sup>1</sup> Toxicity: DNEL not established.

Substance	EG No.
Pentamethyl-piperidyl sebacate	255-437-1

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	<sup>1</sup>	2,35 mg/m <sup>3</sup>	2,5 mg/kg

PNEC (100% component)	
Aquatic Compartment	0,0022 mg/l (Fresh water) 0,00022 mg/l (Sea water) 1,05 mg/kg dry weight (Sediment)
Terrestrial Compartment	0,21 mg/kg

<sup>1</sup> Toxicity: DNEL not established.

Substance	EG No.
Phosphine oxide (100%)	278-355-8

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	<sup>1</sup>	3,5 mg/m <sup>3</sup>	1,00 mg/kg

PNEC (100% component)	
Aquatic Compartment	0,00353 mg/l (Fresh water) 0,000353 mg/l (Sea water) 0,29 mg/kg dry weight (Sediment)
Terrestrial Compartment	0,0557 mg/kg

<sup>1</sup> 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. High-efficiency particulate respirator with full face-piece.
Skin protection	Wear suitable gloves. Butyl and nitrile rubber gloves offer short-term protection. Later surgical gloves offer little 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 A (EN141 or EN405) 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	Clear viscous liquid.
Odour	Ester like
pH	Not applicable
Melting point	Not applicable
Boiling point	> 200°C
Flash point	> 150°C
Flammable limits (lower) (%v/v)	Not applicable
Vapour pressure	-
Solubility (Water)	Not soluble
Solubility	Good solubility with most organic solvents.
Auto ignition temperature	380°C
Explosive properties	Not applicable
Oxidising properties	Not applicable
Relative density	1.1-1.2 (water = 1)
Viscosity	1-2 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 alkalies 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:

#### Methacrylic oligomer (100%)

Skin irritation	Irritating
Eye irritation	Irritating
Skin sensitisation	May cause sensitisation by skin contact.
Aspiration Hazard	No aspiration hazard expected.

#### Glycol methacrylate (100%)

LD50 acute oral rat	> 5000 mg/kg
LD50 acute dermal rabbit	> 5000 mg/kg
Skin irritation (rabbit, 24 h, Draize)	Non-irritant
Eye irritation (rabbit, Draize)	Irritating
Inhalation/skin sensitisation (guinea pig, GPMT)	Sensitizing
Aspiration Hazard	No aspiration hazard expected.
Chronic toxicity oral rat (OESO 422)	> 100 mg/kg
Reproductive toxicity (animal studies)	No suspicion of a toxic effect on reproduction.

#### Pentamethyl-piperidyl sebacate (100%)

LD50 acute oral rat (conventional method)	3,230 mg/kg
Skin irritation (rabbit, OPP 81-5)	Non-irritant
Eye irritation (rabbit, Draize)	Non-irritant
Skin sensitisation guinea pig (OESO 406)	Sensitizing
Aspiration Hazard	No aspiration hazard expected.
Chronic toxicity (animal studies)	No known chronic effects.
Reproductive toxicity (animal studies)	No suspicion of a toxic effect on reproduction.
Experiences in humans	Sensitizing effect by skin contact.

#### Phosphine oxide (100%)

LD50 acute dermal rat	> 2000 mg/kg
Skin irritation (rabbit, 24 h, Draize)	Non-irritant
Eye irritation (rabbit, Draize)	Non-irritant
Skin sensitisation mouse LLNA (OESO 429)	Sensitizing
Aspiration Hazard	No aspiration hazard expected.
Chronic toxicity (animal studies)	May cause damage after repeated ingestion of high doses.
Reproductive toxicity (animal studies)	Suggest a fertility impairing effect.

# SECTION 12: Ecological information

## 12.1. Toxicity

### Methacrylic oligomer (100%)

No data available

### Glycol methacrylate (100%)

Toxicity to fish (mg/l)	LC50 (96 h) ( <i>Oryzias latipes</i> ) (OESO 203)	> 100
Aquatic invertebrates (mg/l)	NOEC (21 d) ( <i>Daphnia magna</i> ) (OESO 202)	24,1
	EC50 (48 h) ( <i>Daphnia magna</i> ) (OESO 202)	380
Aquatic plants (mg/l)	EC50 (72 h) ( <i>Selenastrum capricornutum</i> ) (OESO 201)	836
	NOEC (72 h) ( <i>Selenastrum capricornutum</i> ) (OESO 201)	400
Micro-organisms (mg/l)	EC50 (16 h) ( <i>Pseudomonas fluorescens</i> ) (DEV L8)	> 3,000

### Pentamethyl-piperidyl sebacate (100%)

May cause long-term adverse effects in the aquatic environment. Very toxic (acute effect) to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Toxicity to fish (mg/l)	LC50 (96 h) ( <i>Lepomis macrochirus</i> ) (OECD 203)	0,97
	LC50 (96 h) ( <i>Oncorhynchus mykiss</i> ) (OECD 203)	7,9
	LC50 (96 h) ( <i>Brachydanio rerio</i> ) (OECD 203)	0,9
Aquatic invertebrates (mg/l)	EC50 (24 h) ( <i>Daphnia magna</i> ) (OECD 202)	20
Aquatic plants (mg/l)	EC50 (72 h) ( <i>Desmodesmus subspicatus</i> ) (OECD 201)	1,68
Micro-organisms / effect on activated sludge (mg/l)	EC50 (3 h) (OECD 209)	> 100

### Phosphine oxide (100%)

Acutely toxic for aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Toxicity to fish (mg/l)	LC50 (48 h) ( <i>Oryzias latipes</i> ) (JIS K 0102-71)	6,53
Aquatic invertebrates (mg/l)	EC50 (48 h) ( <i>Daphnia magna</i> ) (OECD 202)	3,53
Aquatic plants (mg/l)	EC50 (72 h) ( <i>Pseudokirchneriella subcapitata</i> ) (OECD 201)	> 2,01
	EC10 (72 h) ( <i>Pseudokirchneriella subcapitata</i> ) (OECD 201)	1,56
Micro-organisms (mg/l)	EC20 (3 h) (OECD 209)	>1,000

## 12.2. Persistence and degradability

### Methacrylic oligomer (100%)

No data available.

### Glycol methacrylate (100%)

Easy biodegradable.

Elimination information:

84% DOC reduction (28 d) (OESO 301 D). Easy biodegradable.

### Pentamethyl-piperidyl sebacate (100%)

Moderately/partially biodegradable. Not readily biodegradable (by OECD criteria).

Elimination information:

38% DOC reduction (28 d) (OECD 301 F) (aerobic, aerobic Micro-organisms).

### Phosphine oxide (100%)

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

Elimination information:

< 20% BOD of the ThOD (28 d) (OECD 301 F) (activated sludge). Poorly biodegradable.

## 12.3. Bioaccumulative potential

### Methacrylic oligomer (100%)

No data available.

### Glycol methacrylate (100%)

Accumulation in organisms is not to be expected.

### Pentamethyl-piperidyl sebacate (100%)

Accumulation in organisms is not to be expected.

### Phosphine oxide (100%)

Does not significantly accumulate in organisms.

Bioconcentration factor: 23 – 55 (56 d), *Cyprinus carpio* (measured): does not significantly accumulate in organisms.

## 12.4. Mobility in soil

### Methacrylic oligomer (100%)

No data available.

### Glycol methacrylate (100%)

The substance will not evaporate into the atmosphere from the water surface. Adsorption to solid soil phase is not expected.

### Pentamethyl-piperidyl sebacate (100%)

The substance will not evaporate into the atmosphere from the water surface. Adsorption to solid soil phase is expected.



#### Phosphine oxide (100%)

The substance will not evaporate into the atmosphere from the water surface. Adsorption to solid soil phase is not expected.

### 12.5. Results of PBT and vPvB assessment

#### Methacrylic oligomer (100%)

PBT: no

vPvB: no

#### Glycol methacrylate (100%)

PBT: no

vPvB: no

#### Pentamethyl-piperidyl sebacate (100%)

PBT: no

vPvB: no

#### Phosphine oxide (100%)

PBT: no

vPvB: no

### 12.6. Other adverse effects

#### Methacrylic oligomer (100%)

Not applicable.

#### Glycol methacrylate (100%)

Do not allow to enter soil, waterways or waste water channels.

#### Pentamethyl-piperidyl sebacate (100%)

Do not allow to enter soil, waterways or waste water channels. Inhibition of degradation activity in activated sludge is not to be anticipated during correct introduction of low concentrations.

#### Phosphine oxide (100%)

Not applicable.

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## 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.

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## 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.

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#### 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%): Glycol Methacrylate and Pentamethyl-piperidyl sebacate.

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### 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

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long-lasting effects.
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264	Wash hands and exposed skin thoroughly after handling.
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: SNOC201701UK

For more information, please contact:

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