Product name: NextDent Ortho Clear

1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

1.1 Product identifier
Product name: NextDent Ortho Clear.
Product description: Monomer based on Acrylic esters.
Alternative names: NextDent 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
Vertex-Dental B.V.
P.O. Box 10
3700 AA Zeist
The Netherlands
info@vertex-dental.com

1.4 Emergency Telephone number
Emergency telephone number: +31 30 6976749
(only available during office hours)

2. 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. 1 H319
- Aquatic acute Cat. 1 H400
- Aquatic chronic Cat. 1 H410

2.2 Label elements

Signal word: Warning
Hazard statement(s):
- H315: Causes skin irritation.
- H317: May cause an allergic skin reaction.
- H319: Causes serious eye irritation.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s)

P280: Wear protective gloves/protective clothing/eye protection/face protection.
P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264: Wash thoroughly after handling.
P272: Contaminated work clothing should not be allowed out of the workplace.
P273: Avoid release to the environment.
P302+P352: IF ON SKIN: Wash with plenty of 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 a rash occurs: Get medical advice/attention.
P62+P364: Take off contaminated clothing and wash it before reuse.
P501: 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].

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>%W/W</th>
<th>EINECS No.</th>
<th>Hazard Class and Category Code(s)</th>
<th>Hazard statement Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methacrylic oligomer</td>
<td>&gt; 70</td>
<td>Proprietary</td>
<td>Skin irrit. Cat 2</td>
<td>H315 H317 H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye irrit. Cat 1</td>
<td></td>
</tr>
<tr>
<td>Glycol Methacrylate</td>
<td>&lt; 20</td>
<td>Proprietary</td>
<td>Skin sens. Cat 1</td>
<td>H317 H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye irrit. Cat 2</td>
<td></td>
</tr>
<tr>
<td>Pentramethyl-piperidyl sebacate</td>
<td>&lt; 5</td>
<td>255-437-1</td>
<td>Skin sens. Cat 1</td>
<td>H317 H400 H410</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic acute Cat 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic chronic Cat 1</td>
<td></td>
</tr>
<tr>
<td>Phosphine oxide</td>
<td>&lt;2.5</td>
<td>278-355-8</td>
<td>Skin sens. Cat 1</td>
<td>H317 H361 H401 H411</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic acute Cat 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic chronic Cat 2</td>
<td></td>
</tr>
</tbody>
</table>

For full text of H phrases see section 16.

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.

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
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 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
In each case, the currently valid national exposure limit values for Dibenzoyl Peroxide, Methyl Methacrylate and dust must be observed.

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC No.</th>
<th>LTEL ppm (8 Hr TWA)</th>
<th>LTEL mg/m³ (8 h TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycol Methacrylate (100%)</td>
<td>212-782-2</td>
<td>0,05</td>
<td>0,24</td>
</tr>
<tr>
<td>DNEL (100% component)</td>
<td>Oral</td>
<td>Inhalation</td>
<td>Dermal</td>
</tr>
<tr>
<td>Worker – Long Term – Systemic effects</td>
<td>1</td>
<td>4,9 mg/m³</td>
<td>1,3 mg/kg</td>
</tr>
</tbody>
</table>

PNEC (100% component)

<table>
<thead>
<tr>
<th>Aquatic Compartment</th>
<th>10 mg/l (Fresh water)</th>
<th>0,482 mg/l (Sea water)</th>
<th>3,79 mg/kg dry weight (sediment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terrestrial Compartment</td>
<td>0,476 mg/kg dry weight</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 Oral toxicity: DNEL not established
2 Long term DNEL is protective of effects resulting from short term exposure
3 Dermal 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.
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 handled 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 Unverträgliche Materialien

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 (rabbit, 24 h, Draize)  Irritating
- Eye irritation (rabbit, Draize)  Irritating
- Skin sensitisation  May cause sensitisation by skin contact.
- Aspiration Hazard  No aspiration hazard expected
Glycol methacrylate (100%)  
LD<sub>50</sub> acute oral rat: > 5000 mg/kg  
LD<sub>50</sub> acute dermal rabbit: > 5000 mg/kg  
Skin irritation (rabbit, 24 h, Draize): non-irritant  
Eye irritation (rabbit, Draize): irritating  
Inhalation (guinea pig, GPMT): sensitizing  
Aspiration Hazard: no aspiration hazard expected  
Chronic toxicity oral rat (OECD 422): > 100 mg/kg  
Reproductive toxicity (animal studies): no suspicion of a toxic effect on reproduction

Avoid contact of the product with skin and eyes and avoid inhalation of vapors of the product.

Pentramethyl-piperidyl sebucate (100%)  
LD<sub>50</sub> 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 (OECD 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%)  
LD<sub>50</sub> acute dermal rat: > 2000 mg/kg  
Skin irritation (rabbit, 24 h, Draize): non-irritant  
Eye irritation (rabbit, Draize): non-irritant  
Skin sensitisation mouse LLNA (OECD 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):  
LC<sub>50</sub> (96 h) (Oryzias latipes) (OECD 203): > 100  
Aquatic invertebrates (mg/l):  
NOEC (21 d) (Daphnia magna) (OECD 202): 24.1  
EC<sub>50</sub> (48 h) (Daphnia magna) (OECD 202): 380  
Aquatic plants (mg/l):  
EC<sub>50</sub> (72 h) (Selenastrum capricornutum) (OECD 201): 836  
NOEC (72 h) (Selenastrum capricornutum) (OECD 201): 400  
Microorganisms (mg/l):  
EC<sub>50</sub> (16 h) (Pseudomonas fluorescens) (DEV L8): > 3,000

Pentramethyl-piperidyl sebucate (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):  
LC<sub>50</sub> (96 h) (Lepomis macrochirus) (OECD 203): 0.97  
LC<sub>50</sub> (96 h) (Oncorhynchus mykiss) (OECD 203): 7.9
LC50 (96 h) (Brachydanio rerio) (OECD 203) 0,9
Aquatic invertebrates (mg/l) EC50 (24 h) (Daphnia magna) (OECD 202) 20
Aquatic plants (mg/l) EC50 (72 h) (Desmodesmus subspicatus) (OECD 201) 1,68
Microorganisms / 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) (Oryzias latipes) (JIS K 0102-71) 6,53
Aquatic invertebrates (mg/l) EC50 (48 h) (Daphnia magna) (OECD 202) 3,53
Aquatic plants (mg/l) EC50 (72 h) (Pseudokirchneriella subcapitata) (OECD 201) >2,01
EC10 (72 h) (Pseudokirchneriella subcapitata) (OECD 201) 1,56
Microorganisms / effect on activated sludge (mg/l)
EC20 (3 h) (OECD 209) 1,000

12.2 Persistence and degradability
Mehtacrylic oligomer (100%)
No data available

Glycol methacrylate (100%)
Easy biodegradable
Elimination information:
84% DOC reduction (28 d) (OECD 301 D) Easy biodegradable

Pentramethyl-piperidyl sebucate (100%)
Moderately/partially biodegradable. Not readily biodegradable (by OECD criteria)
Elimination information:
38% DOC reduction (28 d) (OECD 301 F) (aerobic, aerobic microorganisms)

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
Mehtacrylic oligomer (100%)
No data available.

Glycol methacrylate (100%)
Accumulation in organisms is not to be expected.

Pentramethyl-piperidyl sebucate (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
Mehtacrylic 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.

Pentramethyl-piperidyl sebucate (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
Pentramethyl-piperidyl sebucate (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.

Pentramethyl-piperidyl sebucate (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

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)
14.4 Packing group
Not applicable.

14.5 Environmental hazards
Toxic to aquatic life with long lasting effects.

14.6 Special precautions for user
-

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

SECTION 15: REGULATORY INFORMATION

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

Federal Regulations – Registration status:

Methacrylic oligomer (100%)
Chemical
IECSC (CN) released / listed
EINECS (EU) released / listed
ENCS (J) released / listed
ECL (KOR) released / listed
TSCA (US) released / listed

Glycol methacrylate (100%)
Chemical
REACH (EU) listed
ENCS (J) listed or excepted
DSL (CDN) listed or excepted
AICS (AUS) listed or excepted
METI (J) listed or excepted
ECL (KOR) listed or excepted
PICCS (RP) listed or excepted
IECSC (CN) listed or excepted
ENCS (J) listed or excepted
ECS (Taiwan) listed or excepted
TSCA (US) listed or excepted

Pentamethyl-piperidyl sebucate (100%)
Chemical
TSCA (US) released / listed
REACH (EU) released / listed

Phosphine oxide (100%)
Chemical
TSCA (US) released / listed
REACH (EU) released / listed

15.2 Chemical Safety Assessment
A Chemical Safety Assessment has been carried out for 2-hydroxyethyl Methacrylate.

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.
LEGENDE

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.
Aquatisch akut/chronisch: Hazardous to the aquatic environment.

Full text of H/P/R phrases
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long-lasting effects.

P261: Avoid breathing vapours.
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 to hazardous waste in accordance with local, state or national legislation. Incinerate under approved controlled conditions, using incinerators suitable for the disposal of flammable organics.

This is the end of SDS ID: M-NOC-2015-01-UK