

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, E-Guard, E-Guard M.

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

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

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

Hazard statement(s)

Warning

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].

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. 1 Eye irrit. Cat 1	H315 H317 H319
Glycol Methacrylate	< 20	Proprietary	Skin sens. Cat 1 Eye irrit. Cat 2	H317 H319
Pentramethyl-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.

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.

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

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

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 controlsAppropriate 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 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%)

ISkin 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%)

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 (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

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

Pentramethyl-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
	EC50 (72 h) (<i>Selenastrum capricornutum</i>) (OESO 201)	836
Aquatic plants (mg/l)	NOEC (72 h) (<i>Selenastrum capricornutum</i>) (OESO 201)	400
	EC50 (16 h) (<i>Pseudomonas fluorescens</i>) (DEV L8)	>3,000

Pentramethyl-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) (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) (Desmodemus 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 degradabilityMethacrylic oligomer (100%)

No data available

Glycol methacrylate (100%)

Easy biodegradable

Elimination information:

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

Pentramethyl-piperidyl sebacate (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 potentialMethacrylic oligomer (100%)

No data available.

Glycol methacrylate (100%)

Accumulation in organisms is not to be expected.

Pentramethyl-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 soilMethacrylic 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 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 assessmentMethacrylic oligomer (100%)

PBT: no

vPvB: no

Glycol methacrylate (100%)

PBT: no

vPvB: no

Pentramethyl-piperidyl sebacate (100%)

PBT: no

vPvB: no

Phosphine oxide (100%)

PBT: no

vPvB: no

12.6 Other adverse effectsMethacrylic oligomer (100%)

Not applicable

Glycol methacrylate (100%)

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

Pentramethyl-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

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

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
	HSNO (NZ)	listed or excepted
	ECS (Taiwan)	listed or excepted
	TSCA (US)	listed or excepted

Pentramethyl-piperidyl sebacate (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