

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

1.1 Product identifier

Product name : NextDent™ Ortho IBT

Product description : Monomer based on acrylic esters

Alternative names : Ortho Indirect Bonding Tray

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 trays suitable for placement of orthodontic brackets.

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 :

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

For full text of H phrases see section 16.

2.2. Label elements

Pictogram



Signal word

Warning

Hazard statements	H315 H317 H319	Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.
Precautionary statements	P280 P261 P272 P273 P302+P352 P305+P351+P338 P333+P313 P337+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. If eye irritation persists 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	40 - 60	Proprietary	Skin irrit. Eye irrit.	Cat 2 Cat 2	H315 H319
Ethoxylated Bisphenol A	> 20	Proprietary	Skin irrit. Eye irrit.	Cat 2 Cat 2	H315 H319
Hexyl Methacrylate	< 16	205-521-9	Skin irrit. Eye irrit. STOT SE	Cat 2 Cat 2 Cat 3	H315 H319 H335
Phosphine oxide	< 2,9	278-355-8	Skin sens. Repr. Aquatic acute Aquatic chronic	Cat 1 Cat 2 Cat 2 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 Move into fresh air and keep at rest. Get medical attention if any discomfort continues. If not breathing, give artificial respiration.

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.
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, 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.

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. Avoid breathing vapours, mist or gas. In case of inadequate ventilation, use respiratory protection. Maximize ventilation after accidental release. Avoid contact with skin and eyes. Keep away from hear, sparks and open flame.

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. Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

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 60°C for more than 24 hours. High temperatures may cause spontaneous polymerization.

7.3. Specific end use(s)

Do not store in containers which contain iron or copper.

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

¹ Toxicity: DNEL not established

Substance	EG No.
Ethoxylated Bisphenol A (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.
Hexyl Methacrylate (100%)	205-521-9

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%)	278-355-8

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

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. Later surgical gloves offer little protection. Gloves should be stored correctly and changed regularly, especially if excessive exposure has occurred.

Respiratory protection No need if adequate ventilation is provided. If engineering controls are insufficient or not present, wear suitable respiratory protective equipment.

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	Not applicable
Flash point	Not applicable
Flammable limits (lower) (%v/v)	Not applicable
Vapour pressure	-
Solubility (Water)	Not soluble
Solubility	Good solubility with most organic solvents
Vapour pressure	Not applicable
Explosive properties	Not applicable
Oxidising properties	Not applicable
Relative density	1.05 - 1.20 (water = 1)
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:

Methacrylic oligomer (100%)

Skin irritation (rabbit, 24 h, Draize)	Irritating
Eye irritation (rabbit, Draize)	Irritating
Skin sensitisation	No sensitization
Aspiration Hazard	No aspiration hazard expected

Ethoxylated Bisphenol A (100%)

LD50 acute oral rat	No data available.
LD50 acute dermal rabbit	No data available

Skin irritation (rabbit, 24 h, Draize)	No data available
Eye irritation (rabbit, Draize)	No data available
Aspiration Hazard	No data available
Reproductive toxicity (animal studies)	No suspicion of a toxic effect on reproduction.

Hexyl Methacrylate (100%)

LD50 acute oral rat	No data available
LD50 acute dermal rabbit	No data available
Skin irritation (rabbit, 24 h, Draize)	No data available
Eye irritation (rabbit, Draize)	No data available
Specific target organ toxicity – single exposure	Inhalation – May cause respiratory irritation.
Specific target organ toxicity – repeated exposure	No data available
Aspiration Hazard	No data available
Reproductive toxicity (animal studies)	No suspicion of a toxic effect on reproduction.

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.

Ethoxylated Bisphenol A (100%)

No data available.

Hexyl Methacrylate (100%)

No data available.

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 / effect on activated sludge (mg/l)	EC20 (3 h) (OECD 209)	> 1,000

12.2. Persistence and degradability

Methacrylic oligomer (100%)

No data available.

Ethoxylated Bisphenol A (100%)

No data available.

Hexyl Methacrylate (100%)

No data available.

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.

Ethoxylated Bisphenol A (100%)

No data available.

Hexyl Methacrylate (100%)

No data available.

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.

Ethoxylated Bisphenol A (100%)

No data available.

Hexyl Methacrylate (100%)

No data available.

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

Ethoxylated Bisphenol A (100%)

PBT: no

vPvB: no

Hexyl Methacrylate (100%)

PBT: no

vPvB: no

Phosphine oxide (100%)

PBT: no

vPvB: no

12.6. Other adverse effects

Methacrylic oligomer (100%)

Not applicable.

Ethoxylated Bisphenol A (100%)

Not applicable.

Hexyl Methacrylate (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

No Chemical Safety Assessment has been carried out for the separated components (100%) listed in this document.

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.
H361	Suspected of damaging fertility or the unborn child.
H401	Toxic to aquatic life.
H411	Toxic to aquatic life with long-lasting effects.
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.
P337 + P313	If eye irritation persists 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.

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For more information, please contact:

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A large version of the NextDent logo, with the text "NextDent" in white on a dark blue background with horizontal lines.

www.nextdent.com

NextDent, the leading manufacturer of dental materials for 3D printing.

NextDent B.V. is an independent subsidiary company under the Vertex Global Holding. NextDent's mission is to become the worldwide leading manufacturer of CE-certified and biocompatible dental 3D printing materials. NextDent's Research and Development team is constantly searching for the best possible solutions in order to become a benchmark for 3D printing materials in the dental field. The company's focus is on development of custom-made 3D printing solutions in close cooperation with our customers.

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