

Product name: NextDent Gingiva Mask**1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING****1.1 Product identifier**

Product name NextDent Gingiva Mask.
Product description Monomer based on Acrylic esters.
Alternative names NextDent Gingiva Mask.

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 flexible non-medical Gingiva masks.

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. 2	H401
Aquatic chronic Cat. 2	H411

For full text of H phrases see section 16

2.2 Label elements

Signal word

Warning

Hazard statement(s)

H315: Causes skin irritation.
H319: Causes serious eye irritation.
H401: Toxic to aquatic life.
H411: 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.
 P362+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) No. 1272/2008 [CLP].

Hazardous ingredient(s)	%W/W	EINECS No.	Hazard Class and Category Code(s)	Hazard statement Code(s)
Aliphatic Difunctional Urethane Acrylate	< 50	Proprietary	Skin irrit. Cat 2 Eye irrit. Cat 2	H315 H319
Polypropylene Glycol	> 30	Proprietary	Aquatic chronic Cat 3	H412
Isobornyl Methacrylate	< 20	231-403-1	Aquatic chronic Cat 3	H412
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 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.

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 60°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

Not applicable

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	Pink 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
Auto ignition temperature	Not applicable
Explosive properties	Not applicable
Oxidising properties	Not applicable
Relative density	1.05-1.20 (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:

Aliphatic Difunctional Urethane Acrylate (100%)

Skin irritation (rabbit, 24 h, Draize)	Irritating
Eye irritation (rabbit, Draize)	No sensitization
Skin sensitisation	May cause sensitisation by skin contact.
Aspiration Hazard	No aspiration hazard expected

Polypropylene Glycol (100%)

LD50 acute oral rat	> 2000 mg/kg
LD50 acute dermal rabbit	> 3000 mg/kg
Skin irritation (rabbit, 24 h, Draize)	non-irritant
Eye irritation (rabbit, Draize)	Irritating
Aspiration Hazard	no aspiration hazard expected
Reproductive toxicity (animal studies)	No suspicion of a toxic effect on reproduction

Isobornyl Methacrylate (100%)

LD50 acute oral rat (conventional method)	3.100 - 6700 mg/kg
LD50 acute dermal rabbit	> 3000 mg/kg
Skin irritation (rabbit, OPP 81-5)	slightly irritating
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	No sensitizing effect by skin contact

<u>Phosphine oxide (100%)</u>	
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

Aliphatic Difunctional Urethane Acrylate (100%)

No data available

Polypropylene Glycol (100%)

Aquatic invertebrates (mg/l)	NOEC (21 d) (Daphnia magna) (OESO 202)	>10
	EC50 (48 h) (Daphnia magna) (OESO 202)	≤ 100

Isobornyl Methacrylate (100%)

Toxicity to fish (mg/l)	LC50 (96 h) (Danio rerio) (OECD 202)	1,79
Aquatic invertebrates (mg/l)	EC50 (48 h) (Daphnia magna) (OECD 202)	>2,57
Aquatic plants (mg/l)	EC50 (72 h) (Pseudokirchneriella subcapitata) (OECD 201)	1,68

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

Aliphatic Difunctional Urethane Acrylate (100%)

No data available

Polypropylene Glycol (100%)

Not easy biodegradable

Isobornyl Methacrylate (100%)

Easy biodegradable. (by OECD criteria)

Elimination information:

70% DOC reduction (28 d) (OESO 310)

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

Aliphatic Difunctional Urethane Acrylate (100%)
No data available.

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

Isobornyl Methacrylate (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

Aliphatic Difunctional Urethane Acrylate (100%)
No data available

Polypropylene Glycol (100%)
No data available

Isobornyl Methacrylate (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

Aliphatic Difunctional Urethane Acrylate (100%)

PBT: no

vPvB: no

Polypropylene Glycol (100%)

PBT: no

vPvB: no

Isobornyl Methacrylate (100%)

PBT: no

vPvB: no

Phosphine oxide (100%)

PBT: no

vPvB: no

12.6 Other adverse effects

Aliphatic Difunctional Urethane Acrylate (100%)
Not applicable

Polypropylene Glycol (100%)
Not applicable

Isobornyl 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

A 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.

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.

H319: Causes serious eye irritation.

H401: Toxic to aquatic life.

H411: Toxic to aquatic life with long-lasting effects.

H412: Harmful 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-NGM-2015-01-UK