

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: NextDent SG Orange

Manufacturer: Vertex-Dental

SDS Expiry: 15 February 2029

Supplier Details: Henry Schein New Zealand
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Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6 / 9

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2020
HSR002558

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – May 2025

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form : Mixture
Trade name : NextDent SG
Product group : Trade product

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category : Professional use
Use of the substance/mixture : Manufacture of 3D-printed applications for the dental industry
Use of the substance/mixture : Dentistry

Title	Life cycle stage	Use descriptors
NextDent SG	Professional	SU20

Full text of use descriptors: see section 16

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Vertex-Dental
Centurionbaan 190
3769 AV Soesterberg
The Netherlands
T +31 886160400
info@vertex-dental.com, www.vertex-dental.com

1.4. Emergency telephone number

Emergency number : (Only for the purpose of informing medical personnel in cases of accidental intoxications.
The emergency phone number is 24 hours/day available.)

Country/Area	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	Only for healthcare professionals

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Skin sensitisation, Category 1 H317
Specific target organ toxicity – Single exposure, Category 3, H335
Respiratory tract irritation
Hazardous to the aquatic environment – Chronic Hazard, H412
Category 3

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause respiratory irritation. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. Harmful to aquatic life with long lasting effects.

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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Warning

Contains

: Bisphenol A Polyethylene Glycol Diether Dimethacrylate; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate

Hazard statements (CLP)

: H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H412 - Harmful to aquatic life with long lasting effects.
P261 - Avoid breathing mist, spray.
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.
P501 - Dispose of contents and container to a hazardous or special waste collection point.

Precautionary statements (CLP)

2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	% w/w (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Bisphenol A Polyethylene Glycol Diether Dimethacrylate	CAS-No.: 41637-38-1 EC-No.: 609-946-4	≥ 75	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	CAS-No.: 72869-86-4 EC-No.: 276-957-5 REACH-no: 01-2120751202-68	10 – 20	Skin Sens. 1B, H317 Aquatic Chronic 2, H411

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Name	Product identifier	% w/w (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	CAS-No.: 162881-26-7 EC-No.: 423-340-5 EC Index-No.: 015-189-00-5 REACH-no: 01-2119489401-38	1 – 5	Skin Sens. 1, H317 Aquatic Chronic 4, H413

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Allow affected person to breathe fresh air. Allow the victim to rest. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: If eye irritation persists: Get medical advice/attention. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Eye irritation.
Symptoms/effects after ingestion	: None under normal conditions.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Sand. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: No fire hazard.
Explosion hazard	: No direct explosion hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment. Do not enter fire area without proper protective equipment, including respiratory protection.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection. Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Stop leak if safe to do so. Notify authorities if product enters sewers or public waters.
Absorb spillage to prevent material damage.

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.
Emergency procedures : Ventilate spillage area. Evacuate unnecessary personnel. Avoid breathing mist, spray.
Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures : Ventilate area. Evacuate unnecessary personnel. Stop leak if safe to do so.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb spilled material with sand or earth. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Stop leak without risks if possible.
Methods for cleaning up : Take up liquid spill into absorbent material. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Store away from other materials.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.
Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Use only outdoors or in a well-ventilated area. Avoid breathing mist, spray. Avoid contact with skin and eyes. Wear personal protective equipment.
Handling temperature : < 30
Hygiene measures : Wash hands thoroughly after handling. Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Keep in a cool, well-ventilated place away from heat.
Storage conditions : Keep only in original container. Keep container closed when not in use. To avoid the risks of fires, all contaminated materials should be stored in purpose-built containers or in metal containers with tight-fitting self-closing lids. Store locked up. Store in a well-ventilated place. Keep container tightly closed.
Incompatible products : Strong bases. Strong acids.
Incompatible materials : Sources of ignition. Direct sunlight.
Maximum storage period : 6 months
Storage temperature : < 30 °C
Heat and ignition sources : Direct sunlight.
Storage area : Keep container in a well-ventilated place.
Packaging materials : Store always product in container of same material as original container.

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7.3. Specific end use(s)

No supplementary information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	2 mg/kg bw/day
Long-term - systemic effects, inhalation	3,52 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	0,5 mg/kg bw/day
Long-term - systemic effects, inhalation	0,87 mg/m³
Long-term - systemic effects, dermal	1 mg/kg bw/day
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	1,3 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	3,3 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	0,3 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	0,6 mg/m³
Long-term - systemic effects, dermal	0,7 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0,01 mg/l
PNEC aqua (marine water)	0,001 mg/l
PNEC aqua (intermittent, freshwater)	0,1 mg/l
PNEC aqua (intermittent, marine water)	0,1 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	4,56 mg/kg dwt
PNEC sediment (marine water)	0,46 mg/kg dwt
PNEC (Soil)	
PNEC soil	0,91 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	3,61 mg/l

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8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Wear eye glasses with side protection according to EN 166. Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. EN 13034

Hand protection:

Wear suitable gloves resistant to chemical penetration. The protective gloves to be used must comply with the specifications of the regulation 2016/425 and the resultant standard ISO 374-1. penetration time (maximum wearing period): > 480 m. Suitable material: Nitrile rubber, Chloroprene rubber (0,5mm), Polyvinylchloride (PVC). Layer thickness : 0,4 mm - 0,5 mm - 0,7 mm. If there is a risk of liquid being splashed : Nitrile rubber gloves

8.2.2.3. Respiratory protection

Respiratory protection:

No personal breathing protective equipment is normally required. In case of inadequate ventilation wear respiratory protection. particle filter device (DIN EN 143)

8.2.2.4. Thermal hazards

Thermal hazard protection:

None necessary.

8.2.3. Environmental exposure controls

Environmental exposure controls:

Use appropriate container to avoid environmental contamination. Avoid release to the environment.

Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: dark orange.
Appearance	: Viscous.
Odour	: Characteristic.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available

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Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

VOC content : 0 %

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)	
LD50 oral rat	> 2000 mg/kg bodyweight (OECD 423: Acute Oral Toxicity – Acute Toxic Class Method, Rat, Female, Read-across, Oral, 14 day(s))
LD50 dermal rat	> 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Read-across, Dermal, 15 day(s))

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7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)	
LD50 oral rat	> 5000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity)
LD50 dermal rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), Guideline: EU Method B.3 (Acute Toxicity (Dermal))
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)	
LD50 oral rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity), Remarks on results: other:
LD50 dermal rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), Remarks on results: other:
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)	
NOAEL (animal/male, F0/P)	100 mg/kg bodyweight Animal: rat, Animal sex: male, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test), Guideline: other:
NOAEL (animal/female, F0/P)	300 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test), Guideline: other:
STOT-single exposure	: May cause respiratory irritation.
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)	
NOAEL (oral, rat, 90 days)	1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents), Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)	
NOAEL (oral, rat, 90 days)	100 – 300 mg/kg bodyweight/day
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)	
NOAEL (oral, rat, 28 days)	> 300 mg/kg bodyweight/day
NOAEL (oral, rat, 90 days)	> 1000 mg/kg bodyweight Animal: rat, Guideline: other:92/69/eec
Aspiration hazard	: Not classified
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)	
Viscosity, kinematic	No data available in the literature

11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Avoid release to the environment. Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)	
LC50 - Fish [1]	100 mg/l (4 days)
EC50 - Crustacea [1]	100 mg/l (48h)
EC50 72h - Algae [1]	100 mg/l (72h)
NOEC (chronic)	14,3 mg/l 28 d
NOEC chronic fish	65600 ng/l (34 days)
NOEC chronic crustacea	22400 ng/l (21 days)

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)	
LC50 - Fish [1]	10,1 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 - Crustacea [1]	> 1,2 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	> 0,68 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)
NOEC (acute)	1,2 mg/l 48 hrs
NOEC (chronic)	36,1 mg/l (14 days)

phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)	
LC50 - Fish [1]	> 90 µg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 - Crustacea [1]	> 1175 µg/l Test organisms (species): Daphnia magna
EC50 - Other aquatic organisms [1]	> 1,175 mg/l Test organisms (species): other aquatic crustacea:
EC50 72h - Algae [1]	> 0,26 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)
LOEC (chronic)	0,008 mg/l
NOEC (chronic)	0,008 mg/l (21 d)
NOEC chronic fish	> 0,09 mg/l (96h, Danio rerio)
NOEC chronic algae	0,26 mg/l

12.2. Persistence and degradability

NextDent SG	
Persistence and degradability	Not readily biodegradable in water.
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)	
Persistence and degradability	Not readily biodegradable in water.
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)	
Persistence and degradability	Rapidly degradable
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)	
Persistence and degradability	Not readily biodegradable in water.

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12.3. Bioaccumulative potential

Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)

Partition coefficient n-octanol/water (Log Pow)	5,62 (Practical experience/observation, OECD 117: Partition Coefficient (n-octanol/water), HPLC method)
Bioaccumulative potential	High potential for bioaccumulation (Log Kow > 5).

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)

Partition coefficient n-octanol/water (Log Pow)	3,39 @ 20 °C and pH 7
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phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)

Partition coefficient n-octanol/water (Log Pow)	4,65 – 5,8 @ 20-22 °C and pH 7.5
Bioaccumulative potential	No data available.

12.4. Mobility in soil

Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)

Surface tension	No data available in the literature
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2,56 – 3,88 (log Koc, Calculated value)
Ecology - soil	Low potential for mobility in soil.

12.5. Results of PBT and vPvB assessment

Component

Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Bisphenol A Polyethylene Glycol Diether Dimethacrylate (41637-38-1)

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Can be dumped in according to local regulations.
Additional information	: Do not re-use empty containers.
Ecological information	: Avoid release to the environment.
European List of Waste (LoW, EC 2000/532)	: 18 00 00 - WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)

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HP Code

: HP5 - "Specific Target Organ Toxicity (STOT)/Aspiration Toxicity:" waste which can cause specific target organ toxicity either from a single or repeated exposure, or which cause acute toxic effects following aspiration.
HP4 - "Irritant – skin irritation and eye damage:" waste which on application can cause skin irritation or damage to the eye.
HP13 - "Sensitising:" waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs.
HP14 - "Ecotoxic:" waste which presents or may present immediate or delayed risks for one or more sectors of the environment

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available.				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)		
Reference code	Applicable on	Entry title or description
3(b)	NextDent SG ; Bisphenol A Polyethylene Glycol Diether Dimethacrylate ; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10
3(c)	NextDent SG ; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

VOC Directive (2004/42)

VOC content : 0 %

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Revision date	Modified	
	Supersedes	Modified	
3	Composition/information on ingredients	Modified	
16	Abbreviations and acronyms	Added	

Abbreviations and acronyms:	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
IOELV	Indicative Occupational Exposure Limit Value
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
TRGS	Technical Rules for Hazardous Substances
WGK	Water Hazard Class
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

NextDent SG

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Abbreviations and acronyms:

SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Data sources	: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Other information	: DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

Full text of H- and EUH-statements:

Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Aquatic Chronic 4	Hazardous to the aquatic environment – Chronic Hazard, Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1B	Skin sensitisation, category 1B
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Full text of use descriptors

SU20	Health services
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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Skin Sens. 1	H317	Calculation method
STOT SE 3	H335	Calculation method
Aquatic Chronic 3	H412	Calculation method

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.