

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

1.1. Product identifier

Product form : Mixture
Product name : Ceramill Model 2.0
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
Ceramill Model 2.0	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

Distributor

Amann Girrbach AG
Herrschaftswiesen 1
P.O. Box 6842
Koblach - Austria

Manufacturer

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	Official advisory body	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1 H317
Hazardous to the aquatic environment — Chronic Hazard, Category 4 H413
Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning
Hazardous ingredients : diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
Hazard statements (CLP) : H317 - May cause an allergic skin reaction.
H413 - May cause long lasting harmful effects to aquatic life.
Precautionary statements (CLP) : P280 - Wear protective gloves.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P363 - Wash contaminated clothing before reuse.
P273 - Avoid release to the environment.
P501 - Dispose of contents/container to an approved waste disposal plant.

Ceramill Model 2.0

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

2.3. Other hazards

No additional information available

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]
Ethoxylated bisphenol A dimethacrylate	(CAS-No.) 41637-38-1 (EC-No.) 609-946-4	>= 75	Aquatic Chronic 4, H413
Silicon dioxide substance with national workplace exposure limit(s) (GB)	(CAS-No.) 7631-86-9 (EC-No.) 231-545-4 (REACH-no) 01-2119379499-16	5 - 10	Not classified
Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl methacrylate	(CAS-No.) 7534-94-3 (EC-No.) 231-403-1 (REACH-no) 01-2119886505-27	<10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	(CAS-No.) 75980-60-8 (EC-No.) 278-355-8 (EC Index-No.) 015-203-00-X (REACH-no) 01-2119972295-29	1 - 5	Skin Sens. 1B, H317 Repr. 2, H361f Aquatic Chronic 2, H411

Full text of H-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).
First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest.
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.
First-aid measures after eye contact	: 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.

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

No additional information available

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.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

Ceramill Model 2.0

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible.
Store away from other materials.

6.4. Reference to other sections

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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.

Hygiene measures : Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

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.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Silicon dioxide (7631-86-9)		
Germany	TRGS 910 Acceptable concentration notes	
United Kingdom	WEL TWA (mg/m ³)	6 mg/m ³ (inhalable aerosol) 2,4 mg/m ³ (respirable aerosol)

Ethoxylated bisphenol A dimethacrylate (41637-38-1)

DNEL/DMEL (Workers)

Long-term - systemic effects, dermal	2 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	3,52 mg/m ³

DNEL/DMEL (General population)

Long-term - systemic effects, oral	0,5 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	0,87 mg/m ³
Long-term - systemic effects, dermal	1 mg/kg bodyweight/day

Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl methacrylate (7534-94-3)

DNEL/DMEL (Workers)

Long-term - systemic effects, dermal	1,04 mg/kg bodyweight/day
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DNEL/DMEL (General population)

Long-term - systemic effects, dermal	0,625 mg/kg bodyweight/day
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PNEC (Water)

PNEC aqua (freshwater)	0,00466 mg/l
PNEC aqua (marine water)	0,00000466 mg/l
PNEC aqua (intermittent, freshwater)	0,0179 mg/l

PNEC (Sediment)

PNEC sediment (freshwater)	0,604 mg/kg bw
PNEC sediment (marine water)	0,0604 mg/kg bw

PNEC (Soil)

PNEC soil	0,118 mg/kg bw
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PNEC (STP)

PNEC sewage treatment plant	2,45 mg/l
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Ceramill Model 2.0

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (75980-60-8)

DNEL/DMEL (Workers)

Long-term - systemic effects, dermal	1 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	3,5 mg/m ³

PNEC (Water)

PNEC aqua (freshwater)	0,00353 mg/l
PNEC aqua (marine water)	0,000353 mg/l
PNEC aqua (intermittent, freshwater)	0,0353 mg/l

PNEC (Sediment)

PNEC sediment (freshwater)	0,29 mg/kg bw
PNEC sediment (marine water)	0,029 mg/kg bw

PNEC (Soil)

PNEC soil	0,0557 mg/kg bw
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Titanium dioxide (13463-67-7)

DNEL/DMEL (Workers)

Long-term - local effects, inhalation	10 mg/m ³
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DNEL/DMEL (General population)

Long-term - systemic effects, oral	700 mg/kg bodyweight/day
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PNEC (Water)

PNEC aqua (freshwater)	0,000184 mg/l
PNEC aqua (marine water)	0,0184 mg/l
PNEC aqua (intermittent, freshwater)	0,193 mg/l

PNEC (Sediment)

PNEC sediment (freshwater)	1000 mg/kg bw
PNEC sediment (marine water)	100 mg/kg bw

PNEC (Soil)

PNEC soil	100 mg/kg bw
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PNEC (STP)

PNEC sewage treatment plant	100 mg/l
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8.2. Exposure controls

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 EN 374. penetration time (maximum wearing period): > 480 m. Suitable material: Nitrile rubber, Chloroprene rubber, Polyvinylchloride (PVC). Layer thickness : 0,4 mm - 0,5 mm - 0,7 mm

Eye protection:

Wear eye glasses with side protection according to EN 166.

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

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

Personal protective equipment symbol(s):



Ceramill Model 2.0

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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	: Grey. white. peach.
Odour	: characteristic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: > 400 °C
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,26 g/cm ³
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: 0,7 - 0,8 Pa·s
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

VOC content	: 0 %
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SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

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

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

Ethoxylated bisphenol A dimethacrylate (41637-38-1)

LD50 oral rat	2000 mg/kg
LD50 dermal rat	2000 mg/kg

Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl methacrylate (7534-94-3)

LD50 oral rat	3,16 - 6,81 ml/kg
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Ceramill Model 2.0

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Silicon dioxide (7631-86-9)

LD50 oral rat	> 5000 mg/kg
LD50 dermal rat	> 2000 mg/kg
LC50 inhalation rat (mg/l)	> 5 mg/l/4h

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (75980-60-8)

LD50 oral rat	5000 mg/kg
LD50 dermal rat	2000 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified

Ethoxylated bisphenol A dimethacrylate (41637-38-1)

NOAEL (oral, rat, 90 days)	300 mg/kg bodyweight/day
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Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl methacrylate (7534-94-3)

NOAEL (oral, rat, 90 days)	25 - 500 mg/kg bodyweight/day
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diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (75980-60-8)

LOAEL (oral, rat, 90 days)	250 - 300 mg/kg bodyweight/day
NOAEL (oral, rat, 90 days)	50 - 100 mg/kg bodyweight/day

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Avoid release to the environment.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: May cause long lasting harmful effects to aquatic life.

Ethoxylated bisphenol A dimethacrylate (41637-38-1)

NOEC (chronic)	14,3 mg/l 28 d
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Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl methacrylate (7534-94-3)

LC50 fishes	1,79 mg/l
EC50 Daphnia	2,57 mg/l
EC50 72h algae (1)	2,28 mg/l
NOEC (chronic)	0,233 mg/l (21 d)

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (75980-60-8)

LC50 fishes	6,53 mg/l (48 h)
EC50 Daphnia	3,53 mg/l
EC50 72h algae (1)	2,01 mg/l

12.2. Persistence and degradability

No additional information available

Ceramill Model 2.0

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

12.3. Bioaccumulative potential

Ethoxylated bisphenol A dimethacrylate (41637-38-1)

Log Pow 3,43 - 5,62 @ pH 6.44

Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl methacrylate (7534-94-3)

Log Pow 5,09

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (75980-60-8)

Log Pow 3,1 - 3,87 @ 23 °C and pH 6.4

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.

Product/Packaging disposal recommendations : Can be dumped in according to local regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

Ceramill Model 2.0

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3(b) 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	Ceramill Model 2.0 - Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl methacrylate
3(c) 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	Ceramill Model 2.0 - Ethoxylated bisphenol A dimethacrylate

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Substance(s) are not subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC.

VOC content : 0 %

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

Abbreviations and acronyms:

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
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
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
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STP	Sewage treatment plant

Ceramill Model 2.0

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

TLM	Median Tolerance Limit
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative

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 4	Hazardous to the aquatic environment — Chronic Hazard, Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Repr. 2	Reproductive toxicity, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1B	Skin sensitisation, category 1B
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

Full text of use descriptors	
SU20	Health services

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method
Aquatic Chronic 4	H413	Calculation method

SDS EU (REACH Annex II)

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