

1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name Vertex Monomer Type B
 Product description Monomer based on Methyl Methacrylate
 Alternative names Vertex Self Curing, Vertex Orthoplast, Vertex Orthoplast LP, J-Cryl+ Rapid Repair

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

Identified use Professional: End use of mixtures containing for manufacturing of dental prosthesis, expanding or repairing dental prosthesis, manufacturing of dental regulators and individually formed impression trays.

Uses advised against Mixtures containing unreacted liquid monomer intended to come into contact with skin or nails.

Refer to Exposure Scenario Annex for further details.

1.3 Details of the supplier of the safety data sheet

Vertex-Dental B.V.
 P.O. Box 10
 3700 AA Zeist
 The Netherlands
 info@vertex-dental.com

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

2. SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

According to Regulation (EG) Nr. 1272/2008 [CLP].

| | |
|----------------------------------------|------|
| Flammable Liquid Category 2 | H225 |
| Skin corrosion / irritation Category 2 | H315 |
| Skin sensitization Category 1 | H317 |
| STOT-single exposure Category 3 | H335 |

For full text of H phrases see section 16

2.2 Label elements



Signal word Danger
 Hazard statement(s)
 H225 Highly flammable liquid and vapour.
 H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H335 May cause respiratory irritation.

Precautionary statement(s)
 P210 Keep away from heat, sparks, open flame, hot surfaces – No smoking
 P261 Avoid breathing vapours.
 P280 Wear protective gloves/protective clothing/eye protection/face protection
 P302+P352 IF ON SKIN: Wash with plenty of soap and water.
 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.

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 | EC-No. | Hazard Class and Category Code(s) | Hazard statement Code (s) |
|------------------------------|------|-----------|------------------------------------------------------------------------------------------------------|--------------------------------------|
| Methyl Imethacrylate | > 95 | 201-297-1 | Flam. Liq. 2 Skin Irrit. 2 Skin Sens. 1 STOT SE 3 | H225 H315 H317 H335 |
| Ethylenglycol dimethacrylate | < 5 | 202-617-2 | Skin Sens. 1 STOT SE 3 | H317 H335 |
| N,N-Dimethyl-p-toluidine | < 1 | 202-805-4 | Acute Tox., oral 3 Acute Tox., dermal 3 Acute Tox., inhal. 3 STOT RE 2 Aquatic Chronic 3 | H301 H311 H331 H373 H412 |

SECTION 4: FIRST AID MEASURES
4.1 Description of first aid measures

Inhalation IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTRE or doctor if you feel unwell.

Skin Contact IF ON SKIN (or hair): Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Take off contaminated clothing and wash before reuse.

Eye Contact IF IN EYES: Rinse cautiously with water for several minutes Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical attention.

Ingestion Do not induce vomiting. Rinse mouth. Get immediate medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes skin irritation. May cause respiratory irritation. May cause an allergic skin reaction.

4.3 Indication of the immediate medical attention and special treatment needed

None necessary.

SECTION 5: FIRE-FIGHTING MEASURES**5.1 Extinguishing media**

Suitable Extinguishing Media In case of fire, use water spray, foam, dry powder or CO₂ for extinction. Keep containers cool by spraying with water if exposed to fire.

Unsuitable Extinguishing Media Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Highly flammable liquid and vapour. May polymerise on heating. Sealed containers may rupture explosively if hot.

5.3 Advice for fire-fighters

A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

Eliminate sources of ignition. Wear protective gloves and eye/face protection. Avoid breathing vapours. See section: 8.

6.2 Environmental precautions

Avoid release to the environment. Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body

6.3 Methods and material for containment and cleaning up

Collect spillage. Do not adsorb onto sawdust or other combustible materials. Transfer to a lidded container for disposal or recovery. Use only non-sparking tools.

6.4 Reference to other sections

See section: 8. 13

SECTION 7: HANDLING AND STORAGE**7.1 Precautions for safe handling**

Do not eat, drink or smoke at the work place. Wash thoroughly after handling. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. The vapour is heavier than air; beware of pits and confined spaces. Ground container and receiving equipment. Use explosion proof electrical equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Store in a well-ventilated place. Keep cool. Store locked up. Keep away from heat, sparks, open flame, hot surfaces – No smoking. Protect from sunlight.
IMPORTANT: Methacrylates stored in bulk must be kept in contact with air (oxygen). Monomer vapours are uninhibited and may form polymers in vent or flame arresters, resulting in blockage of vents.
Storage temperature preferably not exceeding 25°C

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

| Substance | EC No. | LTEL ppm (8 Hr TWA) | LTEL mg/m ³ (8Hr TWA) | STEL ppm | STEL mg/m ³ | Notes |
|---------------------|-----------|------------------------|-------------------------------------|-------------|---------------------------|------------|
| Methyl Methacrylate | 201-297-1 | 50 | 208 | 100 | 416 | WEL, IOELV |

| DNEL | Oral | Inhalation | Dermal |
|------------------------------------------|--------------|------------------------|-----------------------------|
| Worker – Long Term – Local effects | ¹ | 210 mg/m ³ | 1,5 mg/cm ² |
| Worker – Long Term – Systemic effects | ¹ | 210 mg/m ³ | 13,67 mg/kg body weight/day |
| Worker – Short Term – Local effects | ¹ | ² | 1,5 mg/cm ² |
| Worker – Short Term – Systemic effects | ¹ | ² | ³ |
| Consumer – Long Term – Local effects | ¹ | 105 mg/m ³ | 1,5 mg/m ² |
| Consumer – Long Term – Systemic effects | ¹ | 74,3 mg/m ³ | 8,2 mg/kg body weight/day |
| Consumer – Short Term – Local effects | ¹ | ² | 1,5 mg/cm ² |
| Consumer – Short Term – Systemic effects | ¹ | ² | ³ |

| | PNEC |
|-------------------------|---------------------------------------------------------------------------------------|
| Aquatic Compartment | 0,94 mg/l (Fresh water) 0,094 mg/l (Sea water) 5,74 mg/kg dry weight (sediment) |
| Terrestrial Compartment | 1,47 mg/kg dry weight |

¹ Oral toxicity: DNEL not established

² Long term DNEL is protective of effects resulting from short term exposure

³ Dermal toxicity: DNEL not established

| Substance | EC No. |
|--------------------------|-----------|
| N,N-Dimethyl-p-toluidine | 202-805-4 |

| DNEL | Oral | Inhalation | Dermal |
|-----------------------------------------|--------------|------------------------|------------|
| Worker – Long Term – Systemic effects | ¹ | 1,35 mg/m ³ | 1,19 mg/kg |
| Consumer – Long Term – Systemic effects | 2,37 mg/kg | 0,34 mg/m ³ | 0,29 mg/kg |

| | PNEC |
|-------------------------|------------------------------------------------------------------------------------------|
| Aquatic Compartment | 0,153 mg/l (Fresh water) 0,0153 mg/l (Sea water) 45,38 mg/kg dry weight (sediment) |
| Terrestrial Compartment | 18,68 mg/kg dry weight |

¹ Oral 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. Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

Individual protection measures, such as personal protective equipment (PPE)

| | |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye/face protection | Wear eye/face protection. Safety spectacles/goggles/full face shield. |
| Skin protection | Wear suitable gloves. The most appropriate glove depends on consideration of a number of factors including the physical strength of the glove, the degree of manual dexterity required, the amount of permeation through the glove material and the duration of wear. There are a wide variety of elastomeric and laminate gloves available. Common elastomeric glove material include latex (natural rubber), neoprene (poly isoprene), nitrile rubber (ABS rubber), butyl rubber, polyvinyl alcohol (PVA), polyvinyl chloride (PVC) and fluoroelastomers. Laminate gloves are made from heat sealed sheets of PVA between layers of polyethylene. In permeations tests PVA/Polyethylene laminate and supported PVA gloves performed best (note that PVA can be rendered ineffective by contact with water if the laminate layer is breached). Butyl and nitrile rubber gloves offer short-term protection. Later surgical gloves offer little protection. Gloves should be stored correctly and changed regularly, especially if excessive exposure has occurred. |
| Respiratory protection | Wear suitable respiratory protective equipment if engineering controls are insufficient, or not present, and exposure to levels above the DNEL is likely. A suitable mask with filter type A (EN141 or EN405) may be appropriate. |
| Other | Keep working clothes separately. Take off contaminated clothing immediately. Keep away from food, drinks and animal feed. |

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

| | |
|---------------------------|---------------------------------------------|
| Form | Liquid |
| Colour | Clear/colourless |
| Odour | Ester like, characteristic strong and acrid |
| pH | Not applicable |
| Melting point | -48 °C |
| Boiling point | 100,5 °C |
| Flash point | 10 °C |
| Flammable Limits (lower) | 2,1 % v/v |
| Flammable Limits (Upper) | 12,5 % v/v |
| Vapour pressure | 3.600 Pa at 20 °C |
| Solubility (Water) | Slightly soluble. 1,6 % at 20 °C |
| Solubility (Other) | Miscible with most organic solvents |
| Auto ignition temperature | 421 °C |
| Explosive properties | Not applicable |
| Oxidising properties | Not applicable |
| Relative density | 0,94 (Water = 1) at 15,5 °C |

9.2 Other information

| | |
|------------------------------|----------------------|
| Minimum Ignition Energy (mJ) | 0,89 – 0,97 at 23 °C |
|------------------------------|----------------------|

SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity**
Will exothermically polymerise in the presence of initiators.
- 10.2 Chemical stability**
Stable in the presence of inhibitor.
- 10.3 Possibility of hazardous reactions**
Susceptible to polymerisation initiated by prolonged storage or the presence of catalyst.
- 10.4 Conditions to avoid**
Heat and direct sunlight.
- 10.5 Incompatible materials**
Polymerisation catalysts, such as peroxy or azo compounds, strong acids, alkalis and oxidising agents. Oxides and salts of transition metals. Organic Nitrogen containing compounds. Cyclohexanone/Cyclohexenol tautomer.
- 10.6 Hazardous Decomposition Product(s)**
Does not decompose up to auto-ignition temperature.

SECTION 11: TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects

(Based on MMA)

Acute toxicity

| | |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Ingestion | Low oral toxicity, but ingestion may cause irritation of the gastrointestinal tract. |
| Ingestion toxicity data | LD50 (Oral) > 5000 mg/kg N,N-Dimethyl-p-toluidine (100%) LD50 (oral) = 1767 mg/kg |
| Ingestion STOT-single exposure | Not applicable. |
| Inhalation | May cause respiratory irritation. May cause drowsiness or dizziness. |
| Inhalation toxicity data | LC50 (vapour) 7093 pp, (29,8 mg/l)(4hr) N,N-Dimethyl-p-toluidine (100%) LC50 (vapour) = 1,4 mg/l |
| Inhalation STOT-single exposure | Exposure to high concentrations may produce adverse effects on the nasal epithelium. |
| Skin Contact | May cause an allergic skin reaction. Causes skin irritation. |
| Skin contact toxicity data | Repeated and/or prolonged contact may cause dermatitis. LD50 (dermal) > 5000 mg/kg N,N-Dimethyl-p-toluidine (100%) >2000 mg/Kg |
| Skin contact STOT-single exposure | Not applicable. |
| Eye Contact | High vapour concentration will cause irritation. |
| Eye contact toxicity data | Slight irritant to rabbit eyes. (OECD 405) |
| Eye STOT-single exposure | Not applicable. |
| Aspiration hazard data | Not an aspiration hazard. |
| <u>Sensitization</u> | |
| Skin sensitization data | Skin sensitization has been reported in studies with guinea pigs. (OECD 406) Evidence of contact sensitization in man. |
| Respiratory sensitization data | Not a respiratory sensitizer. Irritant to the respiratory system and high concentrations may aggravate pre-existing conditions. |

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction).

Carcinogenicity data

No evidence of carcinogenicity. (OECD 451)

Germ cell mutagenicity data

Salmonella typhimurium (TA1535, 153, 97, 98, 100) negative (OECD 71).

Teratogenic and fetotoxic effects only observed in presence of maternal toxicity.

NOAEC (Mouse) = 9.000 ppm

NOAEC (Rat) > 2.028 ppm

Repeated exposure toxicity

Chronic exposure

Repeated exposure to high levels produces adverse effects on the heart, lungs, liver and kidneys. Repeated exposure of animals by inhalation to levels at or above the occupational exposure level produces adverse effects on the nasal epithelium (levels of 100 and 40ppm). There is no reason to believe that Methyl Methacrylate represents a carcinogenic or mutagenic hazard to man based upon evidence from well conducted animal studies, relevant mutagenicity studies and adequate epidemiology studies in relevant cohorts. Recent studies in animals have shown that high exposures do not produce embryo or foetoxic nor teratogenic effects in the presence of maternal toxicity.

STOT – repeated exposure data

NOEL (oral)(rat)(104 weeks) > 2000 pm

NOAEC (inhalation)(rat)(104 weeks) 100 ppm (OECD 453)

NOAEC (inhalation)(mouse)(14 weeks) 1000 ppm (OECD 412)

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Low toxicity to fish.

MMA (100%) LC50 (fish)(typically) > 100 mg/l

MMA (100%) LC50 (fathead minnow)(96 hour)(static) 130 mg/l

DMPT (100%) LC50 (fish)(96 hour) 46 – 52 mg/l

Harmful to aquatic invertebrates.

MMA (100%) EC50 (Daphnia magna)(48 hour) 69 mg/l

Low toxicity to algae

MMA (100%) EC50 (Selenastrum capricornutum)(96 hour) 170 mg/l

MMA (100%) NOEC (zebra fish)(35 days)(flow through) 8,4 mg/l

The product is substantially removed in biological treatment processes.

12.2 Persistence and degradability

Readily biodegradable:

MMA (100%) Chemical Oxygen Demand (COD): 88% (28 days)

Inherent Biodegradation:

Dissolved Organic Carbon Removal (DOC removal): > 95% (28 days)

12.3 Bioaccumulative potential

The product has low potential for bioaccumulation.

12.4 Mobility in soil

The products is predicted to have high mobility in soil

12.5 Results of PBT and vPvB assessment

Not classified as PBT or vPvB.

12.6 Other adverse effects

Not subject to international restrictions.

SECTION 13: DISPOSAL CONSIDERATIONS

Avoid release to the environment. Decontaminate empty drums before recycling.

13.1 Waste treatment methods

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.

SECTION 14: TRANSPORT INFORMATION

14.1 UN-Number

UN 1247

14.2 UN Proper Shipping Name

METHYL METHACRYLATE MONOMER, STABILIZED

14.3 Transport hazard class(es)

| | |
|------------------------------------|----------|
| Class | 3 |
| IMDG-Class | 3 |
| IMDG EMS | F-E, S-D |
| IATA | 3 |
| ADR-Classification Code | F1 |
| ADR HIN | 339 |
| ADR-Transport Category | 2 |
| Tunnel Restriction Code | D/E |
| RID | 3 |
| AND | 3 |
| UK CDG Road: Emergency Action Code | 3YE |

14.4 Packing group

II

14.5 Environmental hazards

Not classified as a Marine Pollutant.

14.6 Special precautions for user

No special requirements.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

Regulation (EC) No 1272/2008 (Classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 107/2006.
 Directive 2009/161/EU (third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 200/39/EC).

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has been carried out for Methyl Methacrylate.

SECTION 16: OTHER INFORMATION

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) No. 453/2010.

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of publication. The information given is designed only as guidance or 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.

The values mentioned in section 8 of this datasheet are based on the invalid values in The Netherlands. Other countries may apply other values.

LEGEND

Note: Not all of the following are necessarily contained in this Safety Data Sheet:folgenden Angaben:

| | |
|------------------------|----------------------------------------------------------------------|
| 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/R phrases

| | |
|--------------------|---------------------------------------------------------------------------------------------------------------|
| H225 | Highly flammable liquid and vapour. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H335 | May cause respiratory irritation. |
| P210 | Keep away from heat, sparks, open flame, hot surfaces – No smoking. |
| P233 | Keep container tightly closed. |
| P240 | Ground/bond container and receiving equipment. |
| P241 | Use explosion-proof electrical/ventilating/lighting/.../ equipment. |
| P242 | Use only non-sparking tools. |
| P243 | Take precautionary measures against static discharge. |
| P261 | Avoid breathing vapours. |
| P264 | Wash (hands and exposed skin) thoroughly after handling. |
| P271 | Use only outdoors or in a well-ventilated area. |
| P272 | Contaminated work clothing should not be allowed out of the workplace. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P302 + P352: | IF ON SKIN: Wash with plenty of soap and water. |
| P303 + P361 + P353 | IF ON SKIN (of hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. |
| P304 + P340: | IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. |
| P312 | Call a POISON CENTRE or doctor if victim feels unwell. |
| P321 | Specific treatment (see on this label). |
| P332 + P313 | If skin irritation occurs: Get medical advice/attention. |
| P333 + P313 | If skin irritation or rash occurs: Get medical advice/attention. |

- P362 Take off contaminated clothing and wash before reuse.
- P363 Wash contaminated clothing before reuse.
- P403 + P233 Store in a well-ventilated place. Keep container tightly closed.
- P403 + P235 Store in a well-ventilated place. Keep cool.
- P405 Store locked up.
- 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-MOB-2015-04-UK