Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.11.2020 *Version number 6* *Revision: 05.03.2020*

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

· **1.1 Product identifier**

· **Trade name: visio.link**

· **Article number:** VLPMMA10
· **1.2 Relevant identified uses of the substance or mixture and uses advised against:**
No further relevant information available.
· **Application of the substance / the mixture:** Primer.

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
bredent GmbH & Co.KG
Weißenhorner Straße 2
89250 Senden
Tel: +49 (0) 7309/872-0
Fax: +49 (0) 7309/872-24

· **Further information obtainable from:**
R & D
e-mail: R.D@bredent.com
· **1.4 Emergency telephone number:** (001) 352 323 3500

SECTION 2: Hazards identification

· **Remark**
The device is a medical device pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. No safety data sheet is required for the device, so no claim is made to full compliance with the relevant statutory requirements.
· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**


GHS02 flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.


GHS05 corrosion

Eye Dam. 1 H318 Causes serious eye damage.


GHS07

Skin Irrit. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
Medical products and medical devices within the meaning of Directives 90/385/EEC and 93/42/EEC used in an invasive manner or in direct contact with the body as well as medical products and medical devices falling under Directive 98/79/EC are fully exempt from the provisions of the CLP Regulation and therefore do not need to be classified, packaged or labelled.
The product is classified and labelled according to the CLP regulation.
· **Hazard pictograms** GHS02, GHS05, GHS07
· **Signal word** Danger

· **Hazard-determining components of labelling:**
2-propenoic acid reaction products with pentaerythritol

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methyl methacrylate

· ***Hazard statements***

H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.

· ***Precautionary statements***

P210 *Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.*
P261 *Avoid breathing dust/fume/gas/mist/vapours/spray.*
P280 *Wear protective gloves/protective clothing/eye protection/face protection.*
P303+P361+P353 *IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].*
P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
P310 *Immediately call a POISON CENTER/doctor.*
P321 *Specific treatment (see on this label).*
P362+P364 *Take off contaminated clothing and wash it before reuse.*
P403+P233 *Store in a well-ventilated place. Keep container tightly closed.*
P403+P235 *Store in a well-ventilated place. Keep cool.*

· ***2.3 Other hazards***

· ***Results of PBT and vPvB assessment***

· ***PBT:*** *Not applicable.*

· ***vPvB:*** *Not applicable.*

SECTION 3: Composition/information on ingredients

· ***3.2 Chemical characterisation: Mixtures***

· ***Description:*** *Mixture of dimethacrylates, initiators and stabilizers.*

· ***Dangerous components:***

CAS: 80-62-6 *EINECS: 201-297-1*	*methyl methacrylate* *Flam. Liq. 2, H225* *Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335*	*40 - 60%*
CAS: 1245638-61-2 *EC number: 629-850-6*	*2-propenoic acid reaction products with pentaerythritol* *Eye Dam. 1, H318* *Aquatic Chronic 2, H411* *Acute Tox. 4, H302; Skin Irrit. 2, H315; Skin Sens. 1, H317*	*< 25%*
CAS: 1565-94-2	*(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate* *Skin Irrit. 2, H315; Eye Irrit. 2, H319*	*< 25%*
CAS: 75980-60-8 *EINECS: 278-355-8*	*diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide* *Repr. 2, H361f*	*< 3%*

· ***Additional information:*** *For the wording of the listed hazard phrases refer to section 16.*

SECTION 4: First aid measures

· ***4.1 Description of first aid measures***

· ***After inhalation:***

Take affected persons into fresh air and keep quiet.
Seek medical treatment in case of complaints.
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.

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· ***After skin contact:***
Seek medical treatment.
Immediately wash with water and soap and rinse thoroughly.
· ***After eye contact:*** *Rinse opened eye for several minutes under running water. Then consult a doctor.*
· ***After swallowing:*** *Rinse out mouth and then drink plenty of water.*
· ***4.2 Most important symptoms and effects, both acute and delayed*** *No further relevant information available.*
· ***4.3 Indication of any immediate medical attention and special treatment needed***
No further relevant information available.

SECTION 5: Firefighting measures

· ***5.1 Extinguishing media***
· ***Suitable extinguishing agents:***
Carbon dioxide
Foam
Fire-extinguishing powder
CO2, sand, extinguishing powder. Do not use water.
· ***For safety reasons unsuitable extinguishing agents:*** *Water with full jet*
· ***5.2 Special hazards arising from the substance or mixture***
Formation of toxic gases is possible during heating or in case of fire.
· ***5.3 Advice for firefighters***
· ***Protective equipment:***
Wear self-contained respiratory protective device.
Wear fully protective suit.
· ***Additional information***
Cool endangered receptacles with water spray.
Collect contaminated fire fighting water separately. It must not enter the sewage system.
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
Ensure adequate ventilation
Wear protective clothing.
Keep away from ignition sources.
Wear protective equipment. Keep unprotected persons away.
· ***6.2 Environmental precautions:***
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
· ***6.3 Methods and material for containment and cleaning up:***
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
Do not flush with water or aqueous cleansing agents
· ***6.4 Reference to other sections***
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling***
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· ***Information about fire - and explosion protection:***
Fumes can combine with air to form an explosive mixture.
Keep ignition sources away - Do not smoke.

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Protect against electrostatic charges.

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage:***
· ***Requirements to be met by storerooms and receptacles:***
Store only in the original receptacle.
Store in a cool location.
· ***Information about storage in one common storage facility:*** *Store away from oxidising agents.*
· ***Further information about storage conditions:***
Store receptacle in a well ventilated area.
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
· ***7.3 Specific end use(s)*** *No further relevant information available.*

*
SECTION 8: Exposure controls/personal protection

· ***Additional information about design of technical facilities:*** *No further data; see item 7.*

· ***8.1 Control parameters***

· ***Ingredients with limit values that require monitoring at the workplace:***	
80-62-6 methyl methacrylate (25-50%)	
WEL (Great Britain)	*Short-term value: 416 mg/m³, 100 ppm* *Long-term value: 208 mg/m³, 50 ppm*

· ***Additional information:*** *The lists valid during the making were used as basis.*

· ***8.2 Exposure controls***
· ***Personal protective equipment:***
· ***General protective and hygienic measures:***
Use skin protection cream for skin protection.
The usual precautionary measures are to be adhered to when handling chemicals.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the skin.
Avoid contact with the eyes and skin.
· ***Respiratory protection:***
Not required if the workplace-related limit values to be monitored are observed (see 8.1).
If workplace exposure limit is exceeded apply Respirator with brown A-type filter.
In case of intensive or longer exposure use self-contained respiratory protective device.
· ***Protection of hands:***
Check protective gloves prior to each use for their proper condition.

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· ***Material of gloves***
Butyl rubber, BR
Recommended thickness of the material: ≥ 0.5 mm
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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· ***Penetration time of glove material***
The penetration time has to be at least 60 minutes (Permeation according to EN 374 Part 3: Level 3).
(based on the main component(s) listed in Section 3.2)
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
· ***Eye protection:***

Tightly sealed goggles

· ***Body protection:*** *Protective work clothing*

SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***	
· ***General Information***	
· ***Appearance:***	
Form:	*Fluid*
Colour:	*Colourless*
· ***Odour:***	*Pungent*
· ***Odour threshold:***	*Not determined.*
· ***pH-value:***	*Not determined.*
· ***Change in condition***	
Melting point/freezing point:	*Undetermined.*
Initial boiling point and boiling range:	*100 °C*
· ***Flash point:***	*10 °C*
· ***Flammability (solid, gas):***	*Undetermined.*
· ***Ignition temperature:***	*430 °C*
· ***Decomposition temperature:***	*Not determined.*
· ***Auto-ignition temperature:***	*Product is not selfigniting.*
· ***Explosive properties:***	*Product is not explosive. However, formation of explosive air/ vapour mixtures are possible.*
· ***Explosion limits:***	
Lower:	*2.1 Vol %*
Upper:	*12.5 Vol %*
· ***Vapour pressure at 20 °C:***	*47 hPa*
· ***Density at 20 °C:***	*1.1 g/cm³*
· ***Relative density***	*Not determined.*
· ***Vapour density***	*Not determined.*
· ***Evaporation rate***	*Not determined.*
· ***Solubility in / Miscibility with water at 20 °C:***	*6 g/l*
· ***Partition coefficient: n-octanol/water:***	*Not determined.*
· ***Viscosity:***	
Dynamic:	*Not determined.*
Kinematic:	*Not determined.*
· ***Solvent content:***	
Organic solvents:	*0.0 %*

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· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions**
Reacts with reducing agents.
Reacts with heavy metals.
Reacts with peroxides and other radical forming substances.
Exothermic polymerisation.
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **Primary irritant effect:**
· **Skin corrosion/irritation**
Causes skin irritation.
· **Serious eye damage/irritation**
Causes serious eye damage.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure**
May cause respiratory irritation.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:**
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
· **12.2 Persistence and degradability** No further relevant information available.
· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.
· **Ecotoxical effects:**
· **Remark:** Harmful to fish
· **Additional ecological information:**
· **General notes:**
Harmful to aquatic organisms
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Must be specially treated adhering to official regulations.
Smaller quantities of cured material may be disposed off together with household waste.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**
· **Recommendation:**
Packaging may be reused or recycled after cleaning.
Packagings that may not be cleansed are to be disposed of in the same manner as the product.

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	UN1247
· **14.2 UN proper shipping name**	
· **ADR**	1247 METHYL METHACRYLATE MONOMER, STABILIZED, ENVIRONMENTALLY HAZARDOUS
· **IMDG, IATA**	METHYL METHACRYLATE MONOMER, STABILIZED
· **14.3 Transport hazard class(es)**	
· **ADR, IMDG, IATA**	

· **Class**	3 Flammable liquids.
· **Label**	3
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	II
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Danger code (Kemler):**	33
· **EMS Number:**	F-E,S-D
· **Stowage Category**	B
· **Stowage Code**	SW2 Clear of living quarters.
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **Transport category**	2
· **Tunnel restriction code**	D/E

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· ***IMDG***	
· ***Limited quantities (LQ)***	*1L*
· ***Excepted quantities (EQ)***	*Code: E2* *Maximum net quantity per inner packaging: 30 ml* *Maximum net quantity per outer packaging: 500 ml*
· ***UN "Model Regulation":***	*UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED, 3, II, ENVIRONMENTALLY HAZARDOUS*

SECTION 15: Regulatory information

· ***15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture***
· ***Labelling according to Regulation (EC) No 1272/2008***
The product is classified and labelled according to the CLP regulation.
· ***Hazard pictograms*** *GHS02, GHS05, GHS07*
· ***Signal word*** *Danger*

· ***Hazard-determining components of labelling:***
2-propenoic acid reaction products with pentaerythritol
methyl methacrylate
· ***Hazard statements***
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.
· ***Precautionary statements***

P210	*Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.*
P261	*Avoid breathing dust/fume/gas/mist/vapours/spray.*
P280	*Wear protective gloves/protective clothing/eye protection/face protection.*
P303+P361+P353	*IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].*
P305+P351+P338	*IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
P310	*Immediately call a POISON CENTER/doctor.*
P321	*Specific treatment (see on this label).*
P362+P364	*Take off contaminated clothing and wash it before reuse.*
P403+P233	*Store in a well-ventilated place. Keep container tightly closed.*
P403+P235	*Store in a well-ventilated place. Keep cool.*

· ***Directive 2012/18/EU***
· ***Named dangerous substances - ANNEX I*** *None of the ingredients is listed.*
· ***Seveso category*** *P5c FLAMMABLE LIQUIDS*
· ***Qualifying quantity (tonnes) for the application of lower-tier requirements*** *5.000 t*
· ***Qualifying quantity (tonnes) for the application of upper-tier requirements*** *50.000 t*
· ***REGULATION (EC) No 1907/2006 ANNEX XVII*** *Conditions of restriction: 3*
· ***15.2 Chemical safety assessment:*** *A Chemical Safety Assessment has not been carried out.*

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· ***Relevant phrases***
H225 Highly flammable liquid and vapour.
H302 Harmful if swallowed.

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H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H361f Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.

· ***Department issuing SDS:*** *R & D*
· ***Contact:*** *R & D*
· ***Abbreviations and acronyms:***
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 4: Acute toxicity - oral – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
· **** Data compared to the previous version altered.***