

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

1.1. Product Identifier

Trade name: ONEshade

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:

dental filling material.

1.3. Details of the supplier of the safety data sheet:

Manufacturer/supplier:

OLIDENT Sp. z o. o., Sp. k.
 32-003 Podtęże 653
 Telephone: +48/12/29-00-502, +48/513/012-992
info@olident.com
www.olident.com

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

Skin Sens. 1 H317 May cause an allergic skin reaction.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008:

The product is classified and labelled according to the CLP regulation



GHS07

Signal word: Warning

Hazard-determining components of labelling:

tetramethylene dimethacrylate.

Hazard statements:

H317 May cause an allergic skin reaction.

Precautionary statements:

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P321 Specific treatment (see on this label).
- P363 Wash contaminated clothing before reuse.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards

Results of PBT and vPvB assessment.

PBT: not applicable

vPvB: not applicable

Section 3: Composition/Information on ingredients

3.1. Chemical characterization

Mixtures

Description:

1,4-Butandioldimethacrylate

Urethandimethacrylate

Bis-GMA

Dangerous components:

CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate		Skin Sens. 1B, H317	2,5-10%
-------------------------------------	-------------------------------	---	---------------------	---------

Additional information For the wording of the listed risk phrases refer to section 16.

Section 4: First aid measures**4.1. Description of first aid measures**

General information - no special measures required.

After inhalation

Supply fresh air; consult doctor in case of complaints.

After skin contact

Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact

Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing

Do not induce vomiting; call for medical help immediately.

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: Fire fighting measures**5.1. Extinguishing media****Suitable extinguishing agents:**

Foam.

Unsuitable extinguishing agents:

Water haze

Carbon dioxide

For safety reasons unsuitable extinguishing agents water with full jet

5.2. Special hazards arising from the substance or mixture

No further relevant information available.

5.3. Advice for fire-fighters

Protective equipment: wear self-contained respiratory protective device.

Section 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Not required.

6.2. Environmental precautions

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).

6.4. Reference to other sections

No dangerous substances are released.

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**

Keep receptacles tightly sealed.

Information about fire - and explosion protection:

Keep ignition sources away - do not smoke. Protect against electrostatic charges.

7.2. Conditions for safe storage, including any incompatibilities**Storage:****Requirements to be met by storerooms and receptacles:**

Close container immediately after use and protect product from light incidence.

Storage between 10 °C and 25 °C.

Information about storage in one common storage facility: Store away from foodstuffs.

Further information about storage conditions:

Protect from heat and direct sunlight.

7.3. Specific end use(s)

No further relevant information available.

Section 8: Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.

8.1. Control parameters
Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: the lists that were valid during the making were used as a basis.

8.2. Exposure control
Personal protective equipment (PPE):
General protective and hygiene measures:

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Protection of hands:

Protective gloves.

Material of gloves

Butyl rubber, BR

Penetration time of glove material

0,1 - 0,2 mm.

Penetration time: 5 min.

Respiratory protection:

Not required.

Eye protection:

Safety glasses

Section 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

General information	
Appearance:	
Form:	Viscous
Colour:	Different according to colouring
Odour:	Weak, characteristic
Odour threshold:	Not determined
pH value:	Not determined
Change in condition:	
Melting point/Melting range:	Undetermined
Boiling point/Boiling range:	251 °C
Flash point:	101 °C
Flammability (solid, gaseous):	Not applicable
Self-igniting:	Product is not self igniting
Danger of explosion:	Product does not present an explosion hazard
Explosion limits:	
Lower:	Not determined
Upper:	Not determined
Vapour pressure:	Not determined
Density:	Not determined
Relative density:	Not determined
Vapour density:	Not determined
Evaporation rate:	Not determined
Solubility in/miscibility with:	
Water:	Not miscible or difficult to mix
Partition coefficient (n-octanol/water):	Not determined.
Viscosity:	
Dynamic:	Not determined
Kinematic:	Not determined
Solvent content:	
Organic solvents:	0,0%

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:

Photoreactive

Danger of polymerization

10.4. Conditions to avoid: no further relevant information available.

10.5. Incompatible materials:

in presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

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.

LD50 values relevant for classification: LD-50 oral >5000mg/Kg (Rat).

Primary irritant effect:

Skin corrosion/irritation based on available data, the classification criteria are not met.

Serious eye damage/irritation based on available data, the classification criteria are not met.

Respiratory or skin sensitisation - may cause an allergic skin reaction.

CMR effects (carcinogenicity, 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 based on available data, the classification criteria are not met.

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 based on available data, the classification criteria are not met.

12.2. Persistence and degradability: no further relevant information available.

12.3. Bio accumulative potential: no further relevant information available.

12.4. Mobility in soil: no further relevant information available.

Additional ecological information:**General notes:**

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

12.6. Other adverse effects: no further relevant information available.

Section 13: Disposal considerations**13.1. Waste treatment methods****Recommendations**

Must be specially treated adhering to official regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

European waste catalogue

08 04 10	waste adhesives and sealants other than those mentioned in 08 04 09
----------	---

Uncleaned packaging**Recommendations**

Packaging that may not be cleansed are to be disposed of in the same manner as the product.

Recommended cleansing agents: alcohol.

Section 14: Transport information

14.1. UN-Number ADR/RID , IMDG, IATA	Void
14.2. UN proper shipping name ADR/RID, IMDG, IATA	Void
14.3. Transport hazard class(es) ADR/RID, IMDG, IATA class	Void
14.4. Packing group ADR/RID, IMDG, IATA	Void
14.5. Environmental hazards: marine pollutant	No
14.6. Special precautions for user	Not applicable
14.7. Transport in bulk according to Annex II of MARPOL and IBC Code	Not applicable
UN "Model Regulation":	Void

Section 15: Regulatory information

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

- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- National regulations
- Technical instructions (air):

Class	Share in %
III	25-10

- Waterhazard class: water hazard class 2 (Self-assessment): hazardous for water.

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
H317 May cause an allergic skin reaction.
- Department issuing MSDS: Olident Sp. z o. o., Sp. K.
- Contact: Dr. med. dent. R. Kuspiel
- 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1