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

1.1. Product identifier

Trade name OVS II Opaquer

REACH Registration No.: if available listed in Chapter. 3

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

Relevant applications identified For dental use only.

1.3. Details of the supplier of the safety data sheet

Company DeguDent GmbH

Postfach 1364 D-63403 Hanau

Telephone +49 (0)6181/59-5767 Telefax +49 (0)6181/59-5879

Email address SDB.Degudent-DE@dentsplysirona.com

1.4. Emergency telephone number

Emergency information +49 (0)6181/59-50 (This telephone number is available during office

hours only.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids Category 2 H225
Skin corrosion/irritation Category 2 H315
Skin Sensitisation Category 1 H317
Specific Target Organ Toxicity - Single exposure Category 3 H335

(inhalation)

2.2. Label elements

Labelling as per (EU) 1272/2008

Statutory basis EU-CLP as per Regulation (EU) No. 1272/2008, Annex VI

hazard-defining component(s) (GHS)

· methyl methacrylate

Hazard pictograms



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Signal word Danger

Hazard statement H225 - Highly flammable liquid and vapour.

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H335 - May cause respiratory irritation.

Precautionary statement: P280 - Wear protective gloves/ eye protection/ face protection.

Prevention P260 - Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking.

Precautionary statement:

ent:

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.

Storage Precaution

Precautionary statement:

Disposal

P501 - Dispose of contents/container in accordance with local regulation.

2.3. Other hazards

When heated, formation of explosive vapour/air mixtures., Danger of bursting of closed systems to vigorous exothermic polymerization. Avoid uncontrolled polymerization.

A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out.

SECTION 3: Composition/information on ingredients

Chemical nature

The preparation contains:, acrylic resin based on: methyl methacrylate, initiators, stabilisers, Pigments

3.1. Substances

_

3.2. Mixtures

Information on ingredients / Hazardous components as per EU-CLP Regulation (EC) No. 1272/2008

• methyl	methacrylate		> 50%					
Skin Sens	sion/irritation	EC-No. - Single exposure	201-297-1 e (inhalation)	Category 2 Category 2 Category 1 Category 3	H225 H315 H317 H335			
• 7,7,9 (or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-diyl-bismethacrylate < 25%								
CAS-No.	72869-86-4	EC-No.	276-957-5					

Texts of H phrases, see in Chapter 16

SECTION 4: First aid measures

4.1. Description of first aid measures

Take off all contaminated clothing immediately.

Inhalation

Move victims into fresh air.

Obtain medical attention.

Skin contact

Wash off immediately with soap and plenty of water.

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Obtain medical attention.

Eye contact

With eye held open, thoroughly rinse immediately with plenty of water for at least 5 minutes. Consult an ophthalmologist.

Ingestion

Do NOT induce vomiting.

Have the mouth rinsed with water.

Have patient drink plenty of water in small sips.

Obtain medical attention.

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

Symptoms

No information available.

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

If skin sensitisation has developed and a causal relationship has been confirmed, further exposure should not beallowed

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: quenching powder

Carbon dioxide (CO2) Alcohol-resistant foam

Unsuitable extinguishing media: Water

5.2. Special hazards arising from the substance or mixture

In case of combustion or decomposition of the product, the fumes produced lead to irritations or inflammations of the respiratory tract.

When heated, formation of explosive vapour/air mixtures.

5.3. Advice for firefighters

In case of fire cool containers or take them to a safe place.

Use water spray to cool unopened containers.

In the case of fire, wear respiratory protective equipment independent of surrounding air and chemical protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Keep unauthorized persons away.

Wear personal protective equipment.

Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Prevent substance from entering soil, natural bodies of water and sewer systems., Avoid penetration into drainage system or in rooms situated at a lower level because of danger of explosion.

6.3. Methods and material for containment and cleaning up

Remove all sources of ignition.

Absorb with liquid-binding material, e.g. inert absorbent, sand, universal binding agents.

Pick up mechanically with a suitable device and collect in a suitable container.

Additional advice

Ensure explosion proofness. Dispose of contaminated material as a waste in a correct manner.

6.4. Reference to other sections

Wear personal protective equipment; see section 8.

Disposal considerations; see section 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Always close container tightly after removal of product.

Avoid light effect heat sun rays.

Vapors are heavier than air.

Only fill up to 90 % of the container as air is required to stabilize.

7.2. Conditions for safe storage, including any incompatibilities

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking.

product is highly flammable.

Vapours are heavier than air and may spread along floors.

Formation of flammable or explosive vapour/air mixtures possible. Danger of explosion

Explosion-proof installations required.

Take precautionary measures against static discharges.

Storage

Keep containers tightly closed in a dry, cool and well-ventilated place.

Ensure there is good room ventilation.

German storage class

3 - Flammable liquids

7.3. Specific end use(s)

We are unaware of any specific end uses which go beyond the data reported in Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

methyl methacrylate					
CAS-No. Control parameters	80-62-6 100 ppm 416 mg/m3	EC-No.	201-297-1 Short Term Exposure Limit (STEL):(EH40 WEL)		
Control parameters	50 ppm 208 mg/m3		Time Weighted Average (TWA):(EH40 WEL)		

8.2. Exposure controls

Engineering measures

Ensure suitable suction/aeration at the work place and with operational machinery.

Personal protective equipment

Respiratory protection

If workplace exposure limit is exceeded apply Respirator with brown A-type filter.

Hand protection

Wear protective gloves made of the following materials: solvent-resistant material.

Glove material butyl-rubber
Material thickness 0.5 mm
Break through time 60 min

Method Source: GESTIS substance database (hazardous substance information system of commercial professional associations)

The suitability for a specific workplace should be discussed with the producers of the protective gloves., The exact break through time can be obtained from the protective glove producer and this has to be observed.

Preventive skin protection, Use barrier cream regularly.

Eye/face protection

goggles

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Skin and body protection

Immediately change moistened and saturated work clothes., Apply adequate skin protection agents before handling the product. Assure skin cleaning and skin care after work. Preventive skin protection is recommended.

Hygiene measures

Do not eat, drink, smoke, or sniff while at work. Wash your hands and/or face before breaks and before termination of work., If workplace exposure limits are exceeded and/or larger amounts are released (leakage, spilling, dust) the indicated respiratory protection should be used., Avoid contact with skin and eyes., After contact with skin, wash immediately with plenty of water., If there is the possibility of skin/eye contact, the indicated hand/eye/body protection should be used.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Form liquid colourless
Odour ester-like

Odour threshold: no data available

pH not applicable

Melting point/range -48.2 °C

tested substance: methyl methacrylate

Boiling point/range 100.3 °C (1013 hPa)

Method: DIN 51 751 tested substance:

methyl methacrylate

Flash point 10 °C

Method: DIN 51 755 tested substance: methyl methacrylate

Evaporation rate no data available

Flammability (solid, gas) no data available

Lower explosion limit 2.1 %(V)

tested substance: methyl methacrylate

Upper explosion limit 12.5 %(V)

tested substance: methyl methacrylate

Vapour pressure 38.7 hPa (20 °C)

tested substance: methyl methacrylate

Density 0.94 g/cm3 (20 °C)

Method: DIN 51757

tested substance:

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methyl methacrylate

Water solubility 15.9 g_l (20 °C)

tested substance: methyl methacrylate

Partition coefficient: n-

octanol/water

POW: 1.38 tested substance:

methyl methacrylate

Autoinflammability Not capable of spontaneous combustion or heating.

Thermal decomposition no data available

Viscosity, dynamic 0.63 mPa.s (20 °C)

Method: Brookfield method

tested substance: methyl methacrylate

Explosiveness Vapours can form explosive mixtures with air.

Oxidizing properties no data available

9.2. Other information

Ignition temperature 430 °C

Method: DIN 51 794

tested substance:, methyl methacrylate

Other information No further physicochemical data were determined.

SECTION 10: Stability and reactivity

10.1. Reactivity

Vapours may form explosive mixture with air.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Possibility of hazardous Danger of bursting of closed systems to vigorous exothermic

reactions polymerization. Avoid uncontrolled polymerization.

10.4. Conditions to avoid

Avoid exposure to light /sunlight, Protect from heat sources of ignition.

10.5. Incompatible materials

Product polymerizes on contact with radical generating substances such as peroxides, azo compounds, heavy metal compounds, solutions.

10.6. Hazardous decomposition products

Heating can release vapours which can be ignited.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute oral toxicity LD50 Rat: > 5000 mg/kg

Method: OECD Test Guideline 401
Test substance: methyl methacrylate

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literature

Acute inhalation toxicity LC50 Rat: 29.8 mg/l / 4 h

Test substance: methyl methacrylate

(literature value)

Acute dermal toxicity LD50 Rabbit: > 5000 mg/kg

Test substance: methyl methacrylate

literature

Skin irritation irritating

Test substance: methyl methacrylate

literature

Eye irritation slightly irritating

Test substance: methyl methacrylate

literature

Sensitization May cause sensitisation by skin contact.

Test substance: methyl methacrylate

literature

Repeated dose toxicity inhalative Rat

Testing period: 2 Jahre NOAEL: 25 mg/kg

target organ/effect: irritative effects, skin linings

Test substance: methyl methacrylate

literature

Oral Rat

Testing period: 2 Jahre NOAEL: 2000 mg/kg

Test substance: methyl methacrylate

drinking water analysis, no therapy-related results, literature

Assessment of STOT single

exposure

no data available

Assessment of STOT repeat

Risk of aspiration toxicity

Gentoxicity in vitro

exposure

no data available

,

positive and negative

Test substance: methyl methacrylate

literature

Gentoxicity in vivo no evidence of mutagenic effects

Test substance: methyl methacrylate

literature

Mutagenicity assessment in vivo: no evidence of mutagenic effects

carcinogenicity assessment no evidence that cancer may be caused, literature., tested substance:,

methyl methacrylate

Toxicity to reproduction no data available

teratogenicity assessment no evidence of teratogenic properties, tested substance:, methyl

methacrylate

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SECTION 12: Ecological information

12.1. Toxicity

Toxicity to fish LC50 Lepomis macrochirus: 191 mg/l / 96 h

Test substance: methyl methacrylate

literature

Oncorhynchus mykiss: > 79 mg/l / 96 h
Test substance: methyl methacrylate

Method: OECD 203

literature

Toxicity in aquatic invertebrates

EC50 Daphnia magna: 68 mg/l / 48 h Test substance: methyl methacrylate

Method: OECD 202

(literature value)

EC50 Daphnia magna: 49 mg/l / 21 d
Test substance: methyl methacrylate
Method: OECD 202 part 2

(literature value)

Toxicity to algae EC50 selenastrum capricornutum: 170 mg/l / 96 h

Test substance: methyl methacrylate

Method: OECD 201

literature

Toxicity to bacteria EC0 Pseudomonas putida: 100 mg/l

Test substance:

methyl methacrylate

literature

12.2. Persistence and degradability

Biodegradability Exposure time: 14 Tage

Result: 94 % Readily biodegradable.

Test substance: methyl methacrylate

Method: OECD 301 C

12.3. Bioaccumulative potential

Bioaccumulation Significant bioaccumulation need not be expected.

12.4. Mobility in soil

the groundwater.

12.5. Results of PBT and vPvB assessment

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A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out.

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12.6. Other adverse effects

Further Information Introduction into soil, natural water bodies or sewerage must be prevented.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product

Disposal according to local authority regulations.

Uncleaned packaging

Disposal according to local authority regulations.

SECTION 14: Transport information

Transport on land (ADR/RID/GGVSEB)

14.1. UN number: UN 1247

14.2. UN proper shipping name: METHYL METHACRYLATE MONOMER, STABILIZED

SOLUTION

14.3. Transport hazard class(es):
14.4. Packing group:
14.5. Environmental hazards:
14.6. Special precautions for user:
Yes

ADR: Tunnel Restriction Code: (D/E)

ADR: Measures as 2.2.3.2.2 ADR/RID/ADN have been applied., Observe listed materials regulation

§35, paragraph 1 GGVSEB

RID: Measures as 2.2.3.2.2 ADR/RID/ADN have been applied.

Inland waterway transport (ADN/GGVSEB (Germany))

14.1. UN number: UN 1247

14.2. UN proper shipping name: METHYL METHACRYLATE MONOMER, STABILIZED

SOLUTION

14.3. Transport hazard class(es):
14.4. Packing group:
14.5. Environmental hazards:
14.6. Special precautions for user:
Yes

Measures as 2.2.3.2.2 ADR/RID/ADN have been applied.

Air transport ICAO-TI/IATA-DGR

14.1. UN number: UN 1247

14.2. UN proper shipping name: Methyl methacrylate monomer, stabilized solution

14.3. Transport hazard class(es):
14.4. Packing group:
14.5. Environmental hazards:
14.6. Special precautions for user:
Yes

IATA-C: FOR USA ONLY: When shipping in, by or via USA note of the Reportable Quantity-

Regulation!

IATA-P: FOR USA ONLY: When shipping in, by or via USA note of the Reportable Quantity-

Regulation!

Sea transport IMDG-Code/GGVSee (Germany)

14.1. UN number: UN 1247

14.2. UN proper shipping name: METHYL METHACRYLATE MONOMER, STABILIZED

SOLUTION

14.3. Transport hazard class(es):14.4. Packing group:II

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14.5. Environmental hazards: -14.6. Special precautions for user: Yes
EmS: F-E,S-D

Clear of living quarters., FOR USA ONLY: When shipping in, by or via USA note of the Reportable

Quantity-Regulation!

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:

for transportapproval see regulatory information

SECTION 15: Regulatory information

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

National legislation

employment restriction Note employment restrictions for pregnant and lactating women., Note

employment restrictions for minors.

15.2. Chemical safety assessment

Chemical safety assessment No Chemical Safety Report as per Articles 2(8), 2(9) or 14 of the REACH

Regulatione is required for this product.

SECTION 16: Other information

Classification and applied procedure to derive the classification of mixtures according to EU Regulation (EC) No. 1272/2008 (CLP)

Classification	Classification procedure
Flam. Liq., 2 , H225	
Skin Corr./Skin Irrit., 2, H315	
Skin.sens., 1 , H317	
STOT SE, 3, H335	

Relevant H phrases from chapter 3

H225 : Highly flammable liquid and vapour.

H315 : Causes skin irritation.

H317 : May cause an allergic skin reaction.
H335 : May cause respiratory irritation.

Further information

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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Legend

ADR European Agreement concerning the International Carriage of Dangerous Goods by

Road

ADN European Agreement concerning the International Carriage of Dangerous Goods by

Inland Waterways

ASTM American Society for Testing and Materials

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ATP Adaptation to Technical Progress

BCF Bioconcentration factor

BetrSichV German Ordinance on Industrial Safety and Health

c.c. closed cup

CAS Chemical Abstract Services

CESIO European Committee of Organic Surfactants and their Intermediates

ChemG German Chemicals Act

CMR carcinogenic-mutagenic-toxic for reproduction

DIN German Institute for Standardization **DMEL** Derived minimum effect level

DNEL Derived no effect level

EINECS European Inventory of Existing Commercial Chemical Substances

EC50 half maximal effective concentration

GefStoffV German Ordinance on Hazardous Substances

GGVSEB German ordinance for road, rail and inland waterway transportation of dangerous

goods

GGVSee German ordinance for sea transportation of dangerous goods

GLP Good Laboratory Practice
GMO Genetic Modified Organism

IATA International Air Transport Association
 ICAO International Civil Aviation Organization
 IMDG International Maritime Dangerous Goods
 ISO International Organization For Standardization

LOAEL Lowest observed adverse effect level

LOELLowest observed effect levelNOAELNo observed adverse effect levelNOECno observed effect concentration

NOEL no observed effect level

o. c. open cup

OECD Organisation for Economic Cooperation and Development

OEL Occupational Exposure Limit
PBT Persistent, bioaccumulative, toxic
PEC Predicted effect concentration
PNEC Predicted no effect concentration

REACH REACH registration

RID Convention concerning International Carriage by Rail

STOT Specific Target Organ Toxicity **SVHC** Substances of Very High Concern

TA Technical Instructions

TPR Third Party Representative (Art. 4)

TRGS Technical Rules for Hazardous Substances
VCI German chemical industry association
vPvB very persistent, very bioaccumulative

VOC volatile organic compounds

VwVwS German Administrative Regulation on the Classification of Substances Hazardous to

Waters into Water Hazard Classes

WGK Water Hazard Class
WHO World Health Organization