

EU SAFETY DATA SHEET

Prepared in accordance with the Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), published in the Official Gazette dated June 23, 2017, and numbered 30105.

(Regulation (EC) No: 1907/2006 Registration, Evaluation, Authorization and Restriction of Chemicals (REACH))

DURADENT ACRYGLAZE

Publication date : 04.04.2024

Revision date :

Version : 00

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

1.1 Product identifier

Trade name: DURADENT ACRYGLAZE

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 Auxillary for dental technology

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Name

: ERK DENTAL MEDİKAL TIBBİ MALZ.TUR.SAN.VE TIC.LTD.ŞTİ

Full address

: TUNA MAH. SANAT CAD. NO: 17 -211

District and Country

: Bornova/İzmir Türkiye

Tel

: +90 232 458 20 55

e-mail address of the competent person responsible for the Safety Data Sheet

: info@erkdental.com

1.4. Emergency telephone number

For urgent inquiries refer to

:+90 232 458 20 55 (Mon. - Fri.: 8:00/13:00 - 13.30/18:00)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2

H225 Highly flammable liquid and vapour.

Skin Irrit. 2

H315 Causes skin irritation.

Skin Sens. 1

H317 May cause an allergic skin reaction.

Repr. 1B

H360Fd May damage fertility. Suspected of damaging the unborn child.

STOT SE 3

H335 May cause respiratory irritation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Exemptions

The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).

Hazard pictograms



GHS02



GHS07



GHS08

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Signal word Danger

Hazard-determining components of labelling:

Methyl methacrylate
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Hazard statements

H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H360Fd May damage fertility. Suspected of damaging the unborn child.
H335 May cause respiratory irritation.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P308+P313 IF exposed or concerned: Get medical advice/attention.
P321 Specific treatment (see on this label).
P362+P364 Take off contaminated clothing and wash it before reuse.
P405 Store locked up.
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

3.2 Mixtures

Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

Dangerous components:		
80-62-6	Methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335 substance with a Community workplace exposure limit	25-<50%
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 1B, H360Fd; Skin Sens. 1B, H317	2.5-<5%
SVHC		
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	

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

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SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Immediately remove any clothing soiled by the product. If symptoms persist consult doctor.

After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

After skin contact:

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

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist consult doctor.

After swallowing:

Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed Allergic reactions

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: CO₂, sand, extinguishing powder. Do not use water.
For safety reasons unsuitable extinguishing agents: Water

5.2 Special hazards arising from the substance or mixture Formation of toxic gases is possible during heating or in case of fire. No further relevant information available.

5.3 Advice for firefighters

Protective equipment: Wear self-contained respiratory protective device.

Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Remove persons from danger area. Keep away from ignition sources. Avoid contact with the eyes and skin. Wear protective clothing.

6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course. Do not allow to penetrate the ground/soil.

6.3 Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Absorb liquid components with liquid-binding material. Dispose of the material collected according to regulations.

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.

Avoid contact with the eyes and skin.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Do not spray onto a naked flame or any incandescent material.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles:

Store in a cool location.

Store only in unopened original receptacles.

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

Further information about storage conditions:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles. Protect from heat and direct sunlight.

Store in a cool place.

7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:		
80-62-6 Methyl methacrylate		
IOELV	Short-term value: 100 ppm Long-term value: 50 ppm	
DNELs		
80-62-6 Methyl methacrylate		
Dermal Inhalative	DNEL dermal DNEL inhalation	13.67 mg/kg bw/day (man) (worker, I. te., syst.) 208 mg/m3 (air) (worker, I. te., syst.)

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

8.2 Exposure controls

Appropriate engineering controls No further data; see section 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Respiratory protection: Suitable respiratory protective device recommended.

Hand protection



Protective gloves

Material of gloves

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.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.



Tightly sealed goggles

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state	: Liquid
Colour	: According to product specification
Odour	: Characteristic
Odour threshold	: Not determined.
Melting point/freezing point	: Undetermined.
Boiling point or initial boiling point and boiling range	: 101 °C
Flammability	: Highly flammable.
Lower and upper explosion limit	
Lower	: Not determined.
Upper	: Not determined.
Flash point	: 10 °C
Auto-ignition temperature	: Undetermined.
Decomposition temperature	: Not determined.
pH	: Not determined.
Viscosity:	
Kinematic viscosity	: Not determined.
Dynamic	: Not determined.
Solubility	
water:	Insoluble.
Partition coefficient n-octanol/water (log value)	: Not determined.
Vapour pressure	: Not determined.
Density and/or relative density	
Density	: Not determined.
Relative density	: Not determined.
Vapour density	: Not determined.
Particle characteristics	: SiO ₂ : Diameter particle structure = 2.5 - 50 nm (TEM, d ₅₀ , number-based) Diameter agglomerate = 5 - 50 mm (laser diffraction dry module, d ₅₀ , volume based)

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9.2 Other information

Appearance:

Form : Fluid

Important information on protection of health and environment, and on safety.

Ignition temperature : Product is not selfigniting.

Explosive properties : Product does not present an explosion hazard.

Solvent content:

VOC (EC) : 0.0 g/l

Change in condition

Evaporation rate : Not determined.

Information with regard to physical hazard classes

Explosives : Void

Flammable gases : Void

Aerosols : Void

Oxidising gases : Void

Gases under pressure : Void

Flammable liquids : Highly flammable liquid and vapour.

Flammable solids : Void

Self-reactive substances and mixtures : Void

Pyrophoric liquids : Void

Pyrophoric solids : Void

Self-heating substances and mixtures : Void

Substances and mixtures, which emit flammable gases in contact with water

Oxidising liquids : Void

Oxidising solids : Void

Organic peroxides : Void

Corrosive to metals : Void

Desensitised explosives : Void

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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 No dangerous reactions known.

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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:		
80-62-6 Methyl methacrylate		
Oral	LD50	6,000 mg/kg (rabbit)
Dermal	LD50	>5,000 mg/kg (rab)
Inhalative	LC50/4 h	29.8 mg/l (rat (f+m))

Primary irritant effect:

Skin corrosion/irritation Causes skin irritation.

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

Respiratory or skin sensitisation May cause an allergic skin reaction.

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 May damage fertility. Suspected of damaging the unborn child.

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.

Additional toxicological information:

Repeated dose toxicity No further relevant information available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

No further relevant information available.

11.2 Information on other hazards

Endocrine disrupting properties

None of the ingredients is listed.

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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

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.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Additional ecological information:

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

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

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

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SECTION 14: Transport information

14.1 UN number or ID number

ADR, IMDG, IATA UN1247

14.2 UN proper shipping name

ADR 1247 METHYL METHACRYLATE MONOMER , STABILIZED mixture
IMDG, IATA METHYL METHACRYLATE MONOMER, STABILIZED mixture

14.3 Transport hazard class(es)

ADR



Class 3 (F1) Flammable liquids.
Label 3

IMDG, IATA



Class 3 Flammable liquids.
Label 3

14.4 Packing group

ADR, IMDG, IATA II

14.5 Environmental hazards:

Marine pollutant: No

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14.6 Special precautions for user

Hazard identification number (Kemler code)

EMS Number

Stowage Category

Stowage Code

Revision date :

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Warning: Flammable liquids.

: 339

: F-E,S-D

: C

: SW1 Protected from sources of heat.

SW2 Clear of living quarters.

14.7 Maritime transport in bulk according to IM instruments

O

: 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

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 MIXTURE, 3, II

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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.

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

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

REGULATION (EU) 2024/590 on substances that deplete the ozone layer

Other regulations, limitations and prohibitive regulations

Substances of very high concern (SVHC) according to REACH, Article 57

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

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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SECTION 16: Other information

Relevant phrases

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H360Fd May damage fertility. Suspected of damaging the unborn child.

Classification according to Regulation (EC) No 1272/2008 Calculation method

Department issuing SDS: Regulatory affairs

Contact: msds@gc.dental

Date of previous version: 22.05.2023

Version number of previous version: 4

Abbreviations and acronyms:

ADR: Accord relatif au transport international 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)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (REACH) LC50:

Lethal concentration, 50 percent LD50:

Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB:

very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 1B: Reproductive toxicity – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Sources

ECHA (<http://echa.europa.eu/>)

EnviChem (www.echemportal.org)

* **Data compared to the previous version altered.** This version replaces all previous versions.

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The information given in this safety data sheet is based on our current knowledge and experience and describes the product in terms of safety-related requirements. The product-related information in this Safety Data Sheet has been compiled from what is known about the individual ingredients.

This Safety Data Sheet examines the product in terms of safety requirements and does not make any guarantees regarding the product's features.

The data here is valid only when the product is used for its appropriate applications. product other are not sold in accordance with applications - in such a case its use may result in risks not mentioned in this list. Do not use for applications you are considering without consulting the manufacturer.

To the best of our abilities, we have tried to provide correct information in this Safety Data Sheet.

All known hazards and information about the product have been tried to be presented to the user.

However, every product is likely to present undiscovered hazards. Our company cannot be held responsible for the consequences that may arise beyond our knowledge and control, depending on the place of use and terms of use. We strongly recommend that users read the information presented in this Safety Data Sheet carefully, understand the way of use thoroughly and make them available to authorized persons. It has been prepared and approved by expert personnel within the framework of the regulation on the Preparation of Safety Data Sheets on Hazardous Substances and Mixtures (Official Gazette 13.12.2014-29204).

PREPARED BY

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Certificate No : -TUV AUSTURIA / 11.60.09
Certificate Date : 25.12.2020
Valid Untill : 25.12.2025