

## 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 DURAPLAST PATTERN RESIN LS Liquid

Publication date : 01.02.2023

Version : 02

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

#### 1.1 Product identifier

Trade name : DURADENT DURAPLAST PATTERN\_RESIN\_LS\_Liquid

#### 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 Auxiliary for dental technology

#### 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier :

ERK DENTAL MEDİKAL TIBBİ MALZ.TUR.SAN.VE TIC.LTD.STİ. Interleuvenlaan 33  
TUNA MAH. SANAT CAD. NO: 17 -211  
Bornova/İzmir Türkiye

Information department : info@erkdental.com

Regulatory affairs

#### 1.4 Emergency telephone number:

Acil Sağlık Hizmetleri: 112 Ulusal Zehir Danışma Merkezi (UZEM)

### 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.

Eye Irrit. 2 H319 Causes serious eye 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.

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### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labeled 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

Signal word Danger

Hazard-determining components of labeling:

Methyl methacrylate ethyl methacrylate

2-(2H-benzotriazol-2-yl)-p-cresol

Ethyleneglycol dimethacrylate

Hazard statements

- |      |  |
|------|--|
| H225 | Highly flammable liquid and vapour.                |
| H315 | Causes skin irritation.                            |
| H319 | Causes serious eye irritation.                     |
| 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/sparks/open flames/hot surfaces. - No smoking.   |
| 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/ 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. |
| 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.

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### SECTION 3: Composition/information on ingredients

#### 3.2 Chemical characterization: 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	50-<75%
	Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
6976-93-8	2-Methoxyethyl methacrylate	10-<25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319	
97-63-2	ethyl methacrylate	5-<10%
	Flam. Liq. 2, H225; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	
3077-12-1	2,2'-[(4-methylphenyl)imino]bisethanol	1-<2.5%
	Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
97-90-5	Ethyleneglycol dimethacrylate	1-<2.5%
	Skin Sens. 1, H317; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: C ≥ 10 %	
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	1-<2.5%
	Acute Tox. 3, H331; Aquatic Chronic 1, H410; Skin Sens. 1, H317	

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

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.

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After eye contact:  
Protect unharmed eye.  
Rinse opened eye for several minutes under running water. Then consult a 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: CO<sub>2</sub>, 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.

## SECTION 6: Accidental release measures

**6.1 Personal precautions, protective equipment and emergency procedures**  
Remove persons from danger area. Keep away from ignition sources  
Wear protective equipment. Keep unprotected persons away. 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.  
Inform respective authorities in case of seepage into water course or sewage system. Do not allow to penetrate the ground/soil.  
In case of seepage into the ground inform responsible authorities. Prevent seepage into sewage system, workpits and cellars.

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### 6.3 Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Absorb liquid components with liquid-binding material. Dispose of the collected material 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 protection against explosions and fires:

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

Do not spray on 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 receptacle 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

Components 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		
Inhalative	DNEL inhalation	mg/m <sup>3</sup> (rat (f+m))
80-62-6 Methyl methacrylate		
Dermal Inhalative	DNEL dermal DNEL inhalation	13.67 mg/kg bw/day (man) (worker, l. te., syst.) 208 mg/m <sup>3</sup> (air) (worker, l. te., syst.)

#### 8.2 Exposure controls

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

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed. 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.

Breathing equipment:

In the event that the limit exposure is exceeded, use a respiratory protective device with filter A. Suitable respiratory protective device recommended.

Protection of hands:



Protective gloves

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### Material of gloves

e.g. KCL Butoject 897 Butyl rubber, BR

Recommended thickness of the material:  $\geq 0.29$  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.

### Penetration time of glove material

For the mixture of chemicals mentioned below the penetration time has to be at least 60 minutes (Permeation according to EN 16523-1:2015: Level 2).

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

### Eye protection:



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### General Information

Physical state	: Fluid
Color	: Clear
Odor	: Characteristic
Odor threshold	: Not determined.
Melting point/Melting range	: Undetermined.
Boiling point/Boiling range	: 100 °C
Flammability (solid, gaseous)	: Highly flammable.
Explosion limits	:
Lower	: 2.1 Vol %
Upper	: 12.5 Vol %
Flash point	: 10 °C
Auto igniting	: Undetermined.
Decomposition temperature	: Not determined

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pH-value:	Not determined.
Viscosity:	
Kinematic:	Not determined.
Dynamic:	Not determined.
Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient (n-octanol/water):	Not determined.
Vapor pressure:	Not determined.
Density and/or relative density	
Density at 20 °C:	0.95 g/cm <sup>3</sup>
Relative density	Not determined.
Vapor density	Not determined.

#### 9.2 Other information

Appearance:	
Form:	Liquid
Important information on protection of health and environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	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	Void
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.

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### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

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

LD/LC50 values that are relevant for classification:

ATEmix (Oral) = 5284 mg/kg

ATEmix (dermal) > 4740 mg/kg

ATEmix (inhal.) = 15 mg/l

80-62-6 Methyl methacrylate		
Oral	LD50	6,000 mg/kg (rabbit)
Dermal Inhalative	LD50 LC50/4 h	>5,000 mg/kg (rab) 29.8 mg/l (rat (f+m))
97-63-2 ethyl methacrylate		
Oral	LD50	13,424 mg/kg (rat (f+m))
Inhalative	LC50/4 h	55 mg/l (rat (f+m))
97-90-5 Ethyleneglycol dimethacrylate		
Oral	LD50	8,700 mg/kg (rat (f+m))
Dermal	LD50	>2,000 mg/kg (rat (f+m))
2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol		
Oral	LD50	10,000 mg/kg (rat (f+m))
Inhalative	LC50/4 h	0.59 mg/l (rat (f+m))

on the skin: Causes skin irritation.

on the eye: Causes serious eye irritation.

Sensitization: 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 Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure May cause respiratory irritation.

Specific target organ toxicity - 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:

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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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		
128-37-0	Butylated hydroxytoluene	List II

## 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

For information on endocrine disrupting properties see section 11.

### 12.7 Other adverse effects

Additional ecological information:

General notes:

Water hazard class 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

Recommendation:

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

European waste catalogue

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing hazardous substances

Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

### SECTION 14: Transport information

#### 14.1 UN-Number

ADR, IMDG, IATA UN1247

#### 14.2 UN proper shipping name

DOT Methyl methacrylate monomer, stabilized

ADR 1247 METHYL METHACRYLATE MONOMER, STABILIZED

IMDG, IATA METHYL METHACRYLATE MONOMER, STABILIZED

#### 14.3 Transport hazard class(es)

ADR



Class 3 (F1) Flammable liquids  
Label 3

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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

Hazard identification number (Kemler code) : 33  
EMS Number : F-E,S-D  
Stowage Category : C  
Stowage Code : SW1 Protected from sources of heat.  
SW2 Clear of living quarters.

Warning: Flammable liquids

### 14.7 Transport in bulk according to Annex II of

MARPOL73/78 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

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

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### SECTION 15: Regulatory information

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

Sara

#### Section 355 (extremely hazardous substances):

None of the ingredient is listed.

#### Section 313 (Specific toxic chemical listings):

80-62-6 Methyl methacrylate

#### Proposition 65

#### Chemicals known to cause cancer:

None of the ingredients is listed.

#### Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

#### Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

#### Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

#### Carcinogenic categories

#### EPA (Environmental Protection Agency)

80-62-6 Methyl methacrylate E, NL

#### TLV (Threshold Limit Value)

80-62-6 Methyl methacrylate A4  
128-37-0 Butylated hydroxytoluene A4

#### MAK (German Maximum Workplace Concentration)

128-37-0 Butylated hydroxytoluene 4

#### NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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

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**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.

**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.  
H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H331 Toxic if inhaled.  
H335 May cause respiratory irritation.  
H410 Very toxic to aquatic life with long lasting effects.

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

Department issuing SDS: Regulatory affairs

Contact: info@erkdental.com

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
- DOT : US Department of Transportation
- 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 vPvB: very Persistent and very Bioaccumulative
- NIOSH : National Institute for Occupational Safety
- OSHA : Occupational Safety & Health
- Flam. Liq. 2 : Flammable liquids – Category 2
- Acute Tox. 4 : Acute toxicity – Category 4
- Acute Tox. 3 : Acute toxicity – Category 3
- Skin Irrit. 2 : Skin corrosion/irritation – Category 2
- Eye Irrit. 2 : Serious eye damage/eye irritation – Category 2 Skin Sens. 1: Skin sensitisation – Category 1
- STOT SE 3 : Specific target organ toxicity (single exposure) – Category 3

## 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 DURAPLAST PATTERN RESIN LS Liquid

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Aquatic Chronic 1 : Hazardous to the aquatic environment - long-term aquatic hazard – Category 1  
Aquatic Chronic 3 : Hazardous to the aquatic environment - long-term aquatic hazard – Category 3  
Sources  
ECHA (<http://echa.europa.eu/>)  
EnviChem ([www.echemportal.org](http://www.echemportal.org))

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