

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 DURACERAM MICROBOND

Publication date : 28.10.2024
Version : 00

Revision date :
Page 1 / 10

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

1.1 Product identifier

Trade name : Duradent DURACERAM MICROBOND

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

Relevant identified uses : Bonded for dental non-precious metal frameworks.
Uses advised against : No relevant information available.

1.3. Details of the supplier of the safety data sheet

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: The product is not classified according to the CLP Regulation.

2.2 Label elements Labelling according to

Regulation (EC) No 1272/2008 : Not applicable
Hazard pictograms : Not applicable
Signal word : Not applicable
Hazard statements : Not applicable

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 characterization:

Mixtures CAS No., Designation: Ceramics Identification number(s): -

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 DURACERAM MICROBOND

Publication date : 28.10.2024
Version : 00

Revision date :
Page 2 / 10

SECTION 4: First aid measures

4.1 Description of first aid measures

General information : No special measures required.

After inhalation : Supply fresh air; seek medical advice if symptoms occur.

After skin contact : Wash with water. In general, the product is not irritating to the skin.

After eye contact : Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor. Irritation occurs due to mechanical effects.

After swallowing : Rinse mouth and drink plenty of water. If symptoms persist, consult a doctor.

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 Suitable extinguishing media Suitable extinguishing media: The product is not flammable. Adapt fire-fighting measures to the surroundings.

Unsuitable extinguishing media: No further relevant information available.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters Special protective equipment:

No special measures required.

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 DURACERAM MICROBOND

Publication date : 28.10.2024
Version : 00

Revision date :
Page 3 / 10

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency measures Procedures to be followed

No special measures required.

6.2 Environmental protection measures

No special measures required.

6.3 Methods and material for containment and cleaning up Collect mechanically.

6.4 Reference to other sections For information on safe handling, see section 7.

For information on personal protective equipment, see section 8.

For disposal information, see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

This product should only be handled by suitably qualified personnel. Avoid dust formation. Ensure good ventilation/ extraction at the workplace.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and containers	: Keep only in the original container.
Advice on storage compatibility	: Not required.
Further information on storage conditions	: None.
Storage class	: Classification according to the Ordinance on Industrial Safety and Health
(BetrSichV): - Specific end use(s)	: No further relevant information available.

7.3 Specific end use(s)

No further relevant information available.

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 DURACERAM MICROBOND

Publication date : 28.10.2024

Version : 00

Revision date :

Page 4 / 10

SECTION 8: Exposure controls/Personal protective equipment

8.1. Control parameters

The product does not contain any relevant quantities of substances with workplace-related limit values that require monitoring. It is recommended to comply with the general dust limit value of 10 mg/m³ (inhalable fraction) / 3 mg/m³ (alveolar fraction).

8.2. Exposure controls

8.2.1 Appropriate engineering controls

No further relevant information available.

8.2.2 Individual protection measures / personal protective equipment

Eye/face protection : Wear safety goggles.

Skin protection : Not required.

Respiratory protection : particle filter P2.

Thermal hazards : Not required.

General protective and hygiene measures : Observe standard occupational hygiene measures. Wash hands before breaks and at the end of work. Do not eat, drink or smoke in areas where the product is worked on.

8.2.3 Environmental exposure controls

No further relevant information available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:

Form : Pasty

Colour : Red

Odour : Odourless Odour

threshold : Not determined.

pH-value : Not applicable.

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 DURACERAM MICROBOND

Publication date : 28.10.2024
Version : 00

Revision date :
Page 5 / 10

Change in condition:

Melting point/Melting range	: Not determined.
Boiling point/boiling range	: Not determined.
Flash point	: Not determined.
Evaporation rate	: Not determined.
Flammability (solid, gaseous)	: Not determined.
Upper/lower flammability or explosive limits	: Not explosive.
Vapor pressure	: Not determined.
Vapor density	: Not determined.
Solubility in water	: Partially soluble, slightly miscible.
Partition coefficient (n-octanol/water)	: Not determined.
Viscosity	: Not determined.
Explosive properties	: Not determined.
Oxidizing properties	: Not determined.

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 Stable under normal handling and storage.

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

None under normal storage and handling conditions.

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 DURACERAM MICROBOND

Publication date : 28.10.2024
Version : 00

Revision date :
Page 6 / 10

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

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.

Further ecological information: Water hazard class 1 (self-assessment): slightly hazardous to water. Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects

No further relevant information available.

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 DURACERAM MICROBOND

Publication date : 28.10.2024
Version : 00

Revision date :
Page 7 / 10

SECTION 13: Disposal considerations

13.1 Waste treatment methods Recommendation:

Dispose of waste in an appropriate landfill or incineration plant in accordance with local regulations.

Uncleaned packaging:

Recommendation: Disposal according to official regulations.

SECTION 14: Transport information

14.1 UN number ADR, ADN, IMDG, IATA: Not applicable

14.2 UN proper shipping name ADR, ADN, IMDG, IATA: Not applicable

14.3 Transport hazard classes ADR, ADN, IMDG, IATA: Class: Not applicable

14.4 Packing group ADR, IMDG, IATA:

Not applicable

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.

Transport/additional information: -

UN "Model Regulation": Not applicable

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 DURACERAM MICROBOND

Publication date : 28.10.2024

Version : 00

Revision date :

Page 8 / 10

SECTION 15: Legal provisions

15.1 Safety, health and environmental protection regulations/specific Regulatory information for the substance or mixture

National regulations: Water hazard

class: WGK 1 (self-assessment): slightly hazardous to water.

Other regulations, restrictions and prohibition regulations: The product is subject to EC Directive 93/42/EEC for medical devices.

15.2 Chemical safety assessment A chemical safety assessment has not been carried out.

SECTION 16: Other information

The above information corresponds to our current level of knowledge and experience and describes only any safety requirements of the product. However, we do not associate this with any guarantee of properties in the sense of statutory warranty regulations.

Abbreviations and acronyms:

ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road (Agreement concerning the International Carriage of Dangerous Goods by Road)

ADN : European Agreement concerning the International Carriage of Dangerous Goods by Road (ADN)

inland waterways)

IMDG : International Maritime Code for Dangerous Goods

IATA : International Air Transport Association

GHS : Globally Harmonized System of Classification and Labeling 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

Further information : Observe the current processing instructions.

Replaces edition: A/02.05.2012 Changes compared to the previous version: All sections.

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 DURACERAM MICROBOND

Publication date : 28.10.2024
Version : 00

Revision date :
Page 9 / 10

Note for users:

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.

This safety data sheet has been created on a voluntary basis.

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product. This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses. Provide appointed staff with adequate training on how to use chemical products.

The details in this document are based on the state of our knowledge at the time of revision. They do not constitute an assurance of the described product properties in terms of statutory warranty requirements. The providing of this document to a recipient does not relieve the recipient of his or her responsibility toward compliance with all laws and stipulations applicable to the product. This applies in particular to the further sale or distribution of the product or substances or items containing the product, in other jurisdictions and with regard to the protection of third-party intellectual property rights. If the described product is processed or mixed with other substances or materials, the details stated in this document cannot be conferred to the resultant new product unless this has been expressly mentioned. If the product is repackaged, the recipient is obligated to additionally provide the required safety-related information. Observed national and local regulations. ERK DENTAL assumes no responsibility for incorrect, improper or non-compliant product use. This new data sheet replaces all previously printed documentation.

All rights reserved. ERK DENTAL Company allows unlimited number of printed outputs to be reproduced, provided that it is used only for internal purposes.

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.

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 DURACERAM MICROBOND

Publication date : 28.10.2024
Version : 00

Revision date :
Page 10 / 10

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

Name/Surname : VİLDAN TUNÇBİLEK CHEMIST / CHEMICAL EVALUATION EXPERT (KDU) TUV AUSTRIA CERTIFIED
Certificate No : -TUV AUSTURIA / 11.60.09
Certificate Date : 25.12.2020
Valid Untill : 25.12.2025