

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 1 / 11

1. Identity of the substance/mixture and company/distributor

1.1 Identity of the substance/mixture

Product Name : DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

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

Areas of use: It is used as a prosthesis in the production of crowns and bridges, replacing the tooth or tooth group.

1.3 Details of the supplier of the safety data sheet

Manufacturer Company : ERK DENTAL MEDİKAL TIBBİ MAL. TYPE. SINGING. VE TİC. LTD. Ş.T.İ.
Head office address: TUNA MAH. ART CAD. NO 17 D:211 CAMDIBI BORNVA IZMIR

Production address: MERİÇ MAH. ART CAD. NO 18 CAMDIBI BORNVA IZMIR

Phone : +90 232 458 20 55

Fax : +90 232 458 20 65

E-mail : info@erkdental.com

1.4 Emergency phone

Company emergency phone: +90 232 458 20 55

Official information center: National Poison Information Center (UZEM) Emergency Tel-114

2. Hazard identification

2.1 Classification of the substance / mixture

Physical damages : Not a dangerous substance

2.2 Label elements : Not a dangerous substance

2.3 Other hazards : This substance/mixture contains no ingredients considered to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 2 / 11

3. Composition/Information on Ingredients

3.1. Substances

Synonyms: Zirconium dioxide
Formula : O_2Zr
Molecular weight: 123.22 g/mol
CAS-No. : 1314-23-4
EC-No: : 215-227-2

3.2. Composition :

| CAS No. | Kimyasal Adı | Bileşen |
|------------|--------------------|------------------|
| 1314-23-4 | Zirconium dioxide | 94.35 ± 0.30 |
| 1314-36-9 | yttrium oxide | 5.65 ± 0.30 |
| 1309-37-1 | iron oxide | <0.020 |
| 1314-28-1 | epyr rryq \$ rhi | $0,25 \pm 0.15$ |
| 1313-59-3 | Sodium oxide | 0.020 |
| 11126-22-0 | Silicon dioxide | 0.020 |

4. First Aid Measures

4.1 Description of first aid measures

If inhaled : Remove person to fresh air, if not breathing give artificial respiration

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 3 / 11

In case of skin contact: Remove contaminated clothing, wash skin with soap and plenty of water, clean clothing before use.

In case of contact with eyes: Flush eyes with plenty of water for 15 minutes, opening eyelids wide.

If swallowed: Do not induce vomiting. If conscious, rinse mouth with plenty of water and drink 2-4 glasses of water. If unconscious, seek medical help.

4.2 Most important symptoms and effects, both acute and delayed : The most important known symptoms and effects are described in the labeling (see section 2.2) and/or section 11.

4.3 Indication of any immediate medical attention and special treatment needed May cause serious eye irritation
No data available

5. Fire Fighting Precautions

5.1 Fire extinguishers

Suitable Extinguishing Media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable Extinguishers : No data available

5.2 Special hazards arising from the substance or mixture

No unusual fire and exposure hazards

5.3 Advice for firefighters: Use an approved positive-pressure self-contained breathing apparatus, wear firefighter's protective clothing

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 4 / 11

6. Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Protective equipment - Emergency Press : Avoid generation of dust. Avoid breathing vapour, mist or gas

6.2 Environmental precautions: No special environmental precautions required

6.3 Methods and materials for containment and cleaning up : Vacuum or sweep material using a HEPA air filter and place in a suitable disposal container. Clean up spills immediately using appropriate protective equipment. Avoid creating dusty conditions. Provide ventilation

6.4. Reference to other sections : See Section 8 for personal protection. See section 11 for additional information on health hazards. See section 13 for waste disposal

7. Handling and Storage

7.1 Precautions for safe handling: Keep away from fire and heat source Provide adequate exhaust ventilation where dust is generated, personnel must have received appropriate training. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Keep container tightly closed, avoid ingestion and inhalation. Do not eat, drink or smoke while using this product

7.2 Conditions for Safe Storage, Including any Incompatibilities : Store in a cool place Keep container tightly closed in a dry and well-ventilated place. Storage class non-flammable solids. Store in its original packaging. Use good cleaning practices during storage, transfer and transportation.

7.3 Specific End Uses : No information available

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 5 / 11

8. Exposure controls/personal protection

8.1 Control parameters

Components with workspace control parameters : Not available

8.2 Exposure controls

Occupational exposure controls
Suitable Equipment



8.2.1. Engineering Measures: Personal protective equipment

Respiratory Protection : If the dust concentration in the air is exceeded, wear self-contained breathing filter mask. Use breathing apparatus in case of emergency rescue or evacuation. A respiratory protection program meeting EN 149 should be followed

Eye / Face Protection : Use safety glasses or chemical safety glasses in accordance with the Eye and face protection regulations specified in EN 166

Skin/Hand Protection : Wear suitable protective gloves and wear suitable protective clothing to avoid skin exposure

8.2.3. Environmental Exposure Control

No special environmental precautions required

9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

a) Appearance Form: powder Color: white

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 6 / 11

- b) Odor No data available
- c) Odor Threshold No data available
- d) pH No data available
- e) Melting point/freezing 2700 °C
- f) Initial boiling point and boiling range 5,000 °C
- g) Flash point Not Applicable
- h) Evaporation rate No data available
- i) Flammability (solid, gas) No data available
- j) Top/bottom No data available flammability or explosive limits
- k) Vapor pressure No data available
- l) Vapor density No data available
- m) Relative density at 25 °C 5.89 g/mL
- n) Water solubility 0.1 g/l - insoluble
- o) Partition coefficient: n- octanol/water No data available
- p) Autoignition temperature No data available
- q) Decomposition temperature No data available
- r) Viscosity No data available
- s) Explosive properties No data available
- t) Oxidizing properties No data available

9.1 Other Information: Not available

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 7 / 11

10. Stability and Responsiveness

10.1 Reactivity: no data

10.2 Chemical stability: Stable at normal temperature

10.3 Possibility of hazardous reactions: no data available

10.4 Conditions to avoid : moisture, flame

10.5 Substances to avoid: Oxidizing agents, strong acids

10.6 Hazardous decomposition products : Irritant and toxic fumes and gases

11. Toxicology Information

11.1 Information on toxicological effects

Acute toxicity: No data available

Respiratory or skin sensitization: No data available. May cause stimulation of eyes and breathing.

Sensitivity: Not available

Skin corrosion/irritation : No data available

Serious eye damage/irritation : Slight eye irritation

Ingestion : No data

Germ cell mutagenicity: none

Carcinogenicity : the product is not carcinogenic

Developmental toxicity: none

No Specific Target Organ Toxicity (single exposure)

Specific Target Organ Toxicity (repeated exposure)

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 8 / 11

Aspiration hazard:

Other relevant toxicity information: To the best of our knowledge, the chemical, physical and toxicological properties have not been studied in detail.(Zirconium dioxide)

12. Ecological Information

12.1 Toxicity

Toxicity to fish mortality LC50 - Brachydanio rerio (zebrafish) - > 100 mg / l - 96 h(Zirconium dioxide)
(OECD Test Guide 203)

Daphnia and other water static test EC50 - Daphnia magna (Water flea) - > 100 mg / l - 48
clock to invertebrates (Zirconium dioxide)
toxicity

12.2 Persistence and degradability: No data available

12.3 Bioaccumulative potential : No data available

12.4 Mobility in soil : No data available

12.5 Results of PBT and vPvB assessment : This substance/mixture contains no ingredients considered persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or greater

12.5 Other adverse effects : No data available

13. Disposal Information

13.1 Waste treatment methods The waste of the product is not hazardous material. Discard as unused product

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 9 / 11

14. Transport Information

14.1. UN Number : None

14.2. UN proper shipping name: None

14.3. Transport hazard class(es) : The product is not a dangerous substance

14.4. Packing group : None

14.5. Environmental hazards : None

14.6. Special precautions for user : None

14.7. Public transport according to Annex II of MARPOL 73/78 and the IBC code : Not available

15. Regulatory Information

15.1 Specific safety, health and environmental legislation for the substance or mixture:

National Regulations

It has been prepared in accordance with Regulation 1907/2006/EC and EU Directive 1999/45/EC. Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

ADR - European Agreement on the International Carriage of Dangerous Goods by Road Packaging Wastes

Control Regulation - (24 August 2011 and No. 28035)

IMDG Code - International Code for Dangerous Goods Transported by Sea

T.R. Ministry of Environment and Urbanization, Waste Management Regulation, dated April 2, 2015, numbered 29314

T.R. Ministry of Environment and Urbanization, dated 11 December 2013, numbered 28848, of Substances and Mixtures

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 10 / 11

Regulation on Classification, Labeling and Packaging.

Republic of Turkey Ministry of Labor and Social Security, dated 6 August 2013, numbered 28730,
Carcinogen and Mutagen
Regulation on Health and Safety Precautions in Working with Substances.

T.R. Ministry of Labor and Social Security, Occupational Health and Safety Law No. 6331, dated 30 June 2012.

T.R. Ministry of Labor and Social Security, dated July 2, 2013, numbered 28695, Personal Protection
Regulation on the use of equipment in workplaces

T.R. Ministry of Labor and Social Security, dated 12 August 2013, numbered 28733, With Chemical
Substances
Regulation on Health and Safety Measures in Studies

15.2 Chemical safety assessment

A chemical safety assessment has not been performed for this product.

16. Other informations

Information for the intended use:

It is aimed to define the product in terms of health, safety and environmental conditions with the matters stated in this form. EBTest Technology Co. is responsible for the matters in the Safety Data Sheet of the product. Ltd. and Safety data sheet based on physical and chemical analyzes given by Erk Dental

Disclaimer:

The user is responsible for taking the aforementioned precautions and having full and complete information about the use of the product. The information provided in this SDS is correct to the best of our knowledge at the time of publication. The information provided is intended only as a guide for safe handling, use, processing, storage, transportation, disposal and release and should not be considered a warranty or quality specification. The information relates only to the specific material specified and may not apply to such material used in combination with any other material or in any process, unless specified in the text.

SAFETY DATA SHEET

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

DURADENT SAPPHIRE ZIRCONIA DISC AND BLOCKS

Preparation Date: 19.12.2018

Revision Date: 25.12.2020

Form No: MS-F-01

Number of Revision: 01

Sayfa 11 / 11

Ad/Soyad
Name /Surname : VILDAN TUNÇBİLEK / KDU-TÜV/ 11.60.09
Belge Tarihi /
Date of issue : 25.12.2020
Geçerlilik Tarihi
Validity : 25.12.2025