EU SAFETY DATA SHEET

according to Reg. (EC) No. 1907/2006

Duradent Dublica B

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Chemical name/Commercial name : **DURADENT DUBLICA B**

Chemical characterization : Poly-siloxane with functional groups + additives

Substance/Mixture : Mixture

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

Intended use : Professional - poly-addition RTV-2 for dental laboratory

Not allowed use : Everyone not specified

1.3 Details of the supplier of the safety data sheet

Manufacturer

ERK DENTAL MEDIKAL TIBBI MALZ.TUR.SAN.VE TIC.LTD.STI

TUNA MAH. SANAT CAD. NO: 17 -211

Bornova/İzmir Türkiye

For urgent inquiries, refer to : 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))

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008:

Not a hazardous substance or mixture.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008:

No labelling according to GHS required.
Safety data sheet available on request.

2.3 Other hazards

The product contains substances, which are relevant for the assessment in chapter 12.5.

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Type	Product	N° CAS	N° CE	Content %	Classification
		REACH N°			
INHA	Quartz	14808-60-7	238-878-4	10 - 20%	STOT RE 1, H372
		Exempt according to Annex V.7			
INHA	Kieselguhr, calcinata in continuo con carbonato di sodio	68855-54-9	272-489-0	0 - 1%	STOT RE 1, H372
		01-2119488518-22-XXXX			

Type: INHA: Ingredient, VERU: Impurity

Quartz and Kieselguhr, calcinata in continuo con carbonato di sodio are embedded in the product and not available as respirable dusts. Due to the product's physical properties, particulate inhalation exposure is not possible.

This product does not contain substances of very high concern (Regulation (EC) No 1907/2006 (REACH), Article 57) in amounts above the permitted limit. The full wording of the risk (R) and hazard (H) phrases is given in section 16 of the sheet.

4. First aid measures

4.1 Description of first aid measures

General information:
In case of accident or if you feel unwell seek medical advice (show label or SDS where possible.

Inhalation:
Material cannot be inhaled under normal conditions.

Skin contact:
Immediately wipe affected skin area with paper towel or cloth. Thoroughly wash skin with soap and water. If symptoms persist, consult a physician (show the label or safety data sheet).

Eye contact:
Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.

Swallowing:
Rinse mouth with water. Never give an unconscious person anything through the mouth. Consult physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation:
None in particular.

Skin contact:
Any relevant information can be found in other parts of this section.

Eye contact:
Any relevant information can be found in other parts of this section.

Swallowing:
Any relevant information can be found in other parts of this section.

4.3 Indication of any immediate medical attention and special treatment needed

Consultation of a physician:
If necessary after first aid.

For rescue team:
Personal protection equipment for the members of the rescue team. Strictly observe the rules of hygiene during and after work.

First aid media:
Emergency shower and eyewash. Remove contaminate clothing immediately.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
Nebulized water, extinguishing powder, foam, carbon dioxide, sand.

Extinguishing media, which shall not to be used for safety reasons:
Full water jet.

5.2 Special hazards arising from the substance or mixture:

Combustion causes harmful smoke. Exposure to combustion products can be hazardous to health. Do not breathe combustion products.

5.3 Advice for firefighters:

General information:
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

Special protective equipment for firefighting:
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137). Remove persons without protective devices.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Secure the area. Wear personal protection equipment (see section 8). Keep unprotected persons away. If material is released indicate risk of slipping. Do not walk through spilled material.

6.2 Environmental precautions

Prevent material from entering surface waters, drains or sewers and soil. Close leak if possible without risk. Contain any fluid that runs out using suitable material (e.g. earth). Retain contaminated water/extinguishing water. Dispose of in prescribed marked containers. Inform authorities if substance leaks into surface waters, sewerage or ground.

6.3 Methods and material for containment and cleaning up

Take up mechanically and dispose of according to local/state/federal regulations. Do not flush away with water. For small amounts: Absorb with a neutral (non-acidic / non-basic) liquid binding material such as diatomaceous earth and dispose of according to government regulations. For large amounts: Liquids may be recovered using suction devices or pumps. If flammable, only air driven or properly rated electrical equipment should be used. Clean any slippery coating that remains using a detergent /soap solution or another biodegradable cleaner. Silicone fluids are slippery; spills are a safety hazard. Apply sand or other inert granular material to improve traction. Observe section 7 disposition.

6.4 Reference to other sections

Relevant information in other sections has to be considered. This applies in particular for information given on personal protective equipment (section 8) and on disposal (section 13).

7. Handling and storage

7.1 Precautions for safe handling

Avoid formation of aerosols. In case of aerosol formation special protective measures are required (exhausting by suction, respiratory protection). Spilled substance increases risk of slipping. Observe information in section 8. Avoid contact with skin and eyes. Wear suitable protective clothing. Keep away from flames. Not smoke.

7.2 Conditions for safe storage, including any incompatibilities

Provide adequate ventilation, and local exhaust as needed. Keep container tightly closed in a cool place. Keep away from heat sources and open flames. Store containers in upright position. Do not drop, drag or bang the container. Do not re-use the empty container. Do not weld. Keep containers tightly closed in a cool, well-ventilated place. Avoid contact with oxidizing substances.

7.3 Specific end use(s)

Information not available.

8. Exposure controls/personal protection

8.1 Control parameters

Not applicable.

Threshold Limit Value:

Not applicable.
Predicted no-effect concentration - PNEC:
Not applicable.
Health - Derived no-effect level - DNEL/DMEL:
Not applicable.

8.2 Exposure controls

Exposure in the work place limited and controlled

General protection and hygiene measures:
Avoid contact with skin, eyes and clothing. Use in accordance with good industrial hygiene and safety rules. Wash hands before breaks and immediately after handling the product. Keep working clothes separately. Use suitable protective gloves and eye/face protection. When using, do not eat, drink or smoke.

Respiratory protection:
In case of dusts/vapours/aerosols being formed or if the limit values like TLV are exceeded: use respiratory equipment with suitable filter (filter type A) or wear a self-contained respiratory apparatus according to EN 371.

Hand protection:
Protective gloves according to EN 374. Glove material: Plastic or rubber. Breakthrough time: > 480 min. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection:
Tightly sealed safety glasses according to EN 166.

Skin protection:
Wear suitable protective clothing.

Exposure to the environment limited and controlled

Prevent material from entering surface waters, drains or sewers and soil. Do not introduce large amounts into purification plants

8.3 Further information for system design and engineering measures

Observe information in section 7. Observe national regulatory requirements.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: paste
Colour	: orange
Odour	: weak
Odour threshold	: some data are not know
pH	: some data are not know
Melting point	: some data are not know
Boiling point	: some data are not know
Flash point	: >200°C (closed cup, ASTM D-56)
Evaporation rate	: some data are not know
Lower flammability/explosive limit	: some data are not know
Upper flammability/explosive limit	: some data are not know
Vapour pressure	: negligible
Water solubility	: not soluble
Vapour density	: some data are not know
Relative density (a 20°C)	: 1.85 g/ml
Partition coefficient (n-octane/water)	: some data are not know
Ignition temperature	: > 450°C
Decomposition temperature	: > 200°C
Viscosity (a 20°C)	: > 1000000 mPa·s
Explosive properties	: some data are not know
Reactive properties	: some data are not know

9.2 Other information

Some data are not know.

10. Stability and reactivity

10.1 Reactivity

If stored and handled in accordance with standard industrial practices no hazardous reactions are known.

10.2 Chemical stability

Product is stable under normal conditions.

10.3 Possibility of hazardous reactions

Will not occur.

10.4 Condition to avoid

Keep away from heat sources. Protect from water and humidity.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Thermal breakdown of this product during fire or very high heat condition may evolve the following hazardous decomposition products: silicium dioxide, traces of incompletely burned carbon compounds, nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Route of exposure	Result/Effect	Species/Test system	Source
Oral	LD_{50}: > 2000 mg/kg	Rat	Conclusion by analogy
Inhalation	-	-	-
Skin	LD_{50}: > 2000 mg/kg	Rat	Conclusion by analogy

Skin corrosion/irritation

Result/Effect	Species/Test system	Source
Not irritating	Rabbit	Conclusion by analogy

Serious eye damage/eye irritation

Result/Effect	Species/Test system	Source
Not irritating	Rabbit	Conclusion by analogy

Respiratory or skin sensitization

Route of exposure	Result/Effect	Species/Test system	Source
Dermal	Not sensitizing	Guinea-pig; Bühler	Conclusion by analogy OECD 406

Germ cell mutagenicity
For this endpoint, no toxicological test data is available for the whole product.

Carcinogenicity
For this endpoint, no toxicological test data is available for the whole product.

Reproductive toxicity
For this endpoint, no toxicological test data is available for the whole product.

Specific target organ toxicity (single exposure)
For this endpoint, no toxicological test data is available for the whole product.

Specific target organ toxicity (repeated exposure)
For this endpoint, no toxicological test data is available for the whole product.

Aspiration hazard
Based on the physical-chemical properties of the product no aspiration hazard must be expected.

12. Ecological information

12.1 Toxicity

Assessment based on eco-toxicological tests with similar products under consideration of the physical-chemical properties: for this product no effects on aquatic organisms, relevant for classification, are expected. According to current knowledge adverse effects on water purification plants are not expected.

12.2 Persistence and degradability

Silicone content: biologically not degradable. Separation by sedimentation.

12.3 Bioaccumulative potential

Polymer component: No adverse effects expected.

12.4 Mobility in soil

Silicone content: Insoluble in water.

12.5 Results of PBT and vPvB assessment

Some data are not know.

12.6 Other adverse effects

In order to avoid contamination, do not allow the substance to drain into groundwater, into streams or drains.

13. Disposal considerations

13.1 Waste treatment methods

Material that cannot be used, reprocessed or recycled should be disposed of in accordance with Federal, State, and local regulations at an approved facility. Depending on the regulations, waste treatment methods may include, e.g., landfill or incineration.

13.2 Uncleaned packaging

Completely discharge containers (no tear drops, no powder rest, scraped carefully). Containers may be recycled or re-used. Observe local/state/federal regulations. Uncleaned packaging should be treated with the same precautions as the material.

13.3 Waste Disposal Legislation Ref.No.(EC)

It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste-disposal operator.

14. Transport information

14.1 UN number

Not regulated for transport.

14.2 UN proper shipping name

Not regulated for transport.

14.3 Transport hazard class(es)

Not regulated for transport.

14.4 Packing group

Not regulated for transport.

14.5 Environmental hazards

Not applicable.

14.6 Special precaution for user

Relevant information in other sections has to be considered.

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

Bulk transport in tankers is not intended. (Attac. II of Marpol 73/78, IBC code).

15. Regulatory information

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

National and local regulations must be observed. For label information refer to section 2 of this sheet.

15.2 Chemical safety assessment

Some data are not know.

16. Other information

16.1 Product

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.

16.2 Other information

Bibliography:

Regulation (EC) 1907/2006 (REACH) of the European Parliament
Regulation (EC) 1272/2008 (CLP) of the European Parliament
Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
Regulation (EC) 453/2010 of the European Parliament
Regulation (EC) 830/2015 of the European Parliament
Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
Regulation (EC) 487/2013 (IV Atp. CLP) of the European Parliament
Regulation (EC) 944/2013 (V Atp. CLP) of the European Parliament
Regulation (EC) 605/2014 (VI Atp. CLP) of the European Parliament

Test of hazard (H) phrases mentioned in section 2-3 of this sheet:

STOT RE 1: Specific target organ toxicity - repeated exposure 1
H372 Causes damage to organs through prolonged or repeated exposure.

Note:

n.d. : not determined
n.a. : not applicable

Information Source and References

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DÜZENLEYEN

Ad/Soyad	:	VİLDAN TUNÇBİLEK KİMYAGER / KİMYASAL DEĞERLENDİRME UZMANI (KDU) TUV AVUSTURYA SERTİFİKALI
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- End of Safety Data Sheet -