Safety data sheet

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

1.1. Product identifier

Product name	**DURADENT DURAFLEX LIGHT**

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

Identified Uses	Industrial	Professional	Consumer
For professional use only. Condensation silicone for dental impression material.	-		-

1.3. Details of the supplier of the safety data sheet

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

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments. Hazard classification and indication:

2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements:

EUH210	Safety data sheet available on request.
EUH208	Contains: D-LIMONENE. May produce an allergic reaction.

Precautionary statements: --

2.3. Other hazards.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
CRISTOBALITE		
CAS. 14464-46-1	10 - 20	STOT RE 1 H372
EC. 238-455-4		
INDEX. -		
D-LIMONENE		
CAS. 5989-27-5	0,04 - 0,25	Flam. Liq. 3 H226, Asp. Tox. 1 H304, Skin Irrit. 2 H315, Skin Sens. 1 H317, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410
EC. 227-813-5		
INDEX. 601-029-00-7		

Note: Upper limit is not included into the range.

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures.

4.1. Description of first aid measures.

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

4.2. Most important symptoms and effects, both acute and delayed.

For symptoms and effects caused by the contained substances, see chap. 11.

4.3. Indication of any immediate medical attention and special treatment needed.

Information not available.

SECTION 5. Firefighting measures.

5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT
Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.
UNSUITABLE EXTINGUISHING EQUIPMENT
Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Excess pressure may form in containers exposed to fire at a risk of explosion. 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 FIRE-FIGHTERS
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).

SECTION 6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency procedures.

Block the leakage if there is no hazard.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage.

7.1. Precautions for safe handling.

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

Information not available.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

Regulatory References:

BEL	Belgique	AR du 11/3/2002. La liste est mise à jour pour 2010
CHE	Suisse / Schweiz	Valeurs limites d`exposition aux postes de travail 2012. / Grenzwerte am Arbeitsplatz
DEU	Deutschland	MAK-und BAT-Werte-Liste 2012
DNK	Danmark	Graensevaerdier per stoffer og materialer
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
IRL	Éire	Code of Practice Chemical Agent Regulations 2011
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
NLD	Nederland	Databank of the social and Economic Concil of Netherlands (SER) Values, AF 2011:18
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2014

CRISTOBALITE
Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
VLEP	BEL	0,05				RESP.
VEL	CHE	0,15				RESP.
MAK	CHE	0,15				RESP.
TLV	DNK	0,15				RESP.
VLEP	FRA	0,05				RESP.
OEL	IRL	0,1				RESP.
TLV	ITA	0,05				(USA-NIOSH)
MAC	NLD	0,075				RESP.
MAK	SWE	0,05				RESP.
TLV-ACGIH		0,025				

D-LIMONENE
Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
VEL	CHE	110		220		INHAL.
MAK	CHE	110		220		INHAL.
MAK	DEU	28		110		INHAL.

Predicted no-effect concentration - PNEC.		
Normal value in fresh water	0,0054	mg/l
Normal value in marine water	0,00054	mg/l
Normal value for fresh water sediment	1,32	mg/kg
Normal value for marine water sediment	0,13	mg/kg
Normal value of STP microorganisms	1,8	mg/l
Normal value for the terrestrial compartment	0,262	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Oral.			VND	4,76 mg/kg/d				
Inhalation.			VND	8,33 mg/m3			VND	8,33 mg/m3
Skin.	0,111 mg/cm2	VND			0,222 mg/cm2	VND		

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration. Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION
Wear category III professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION
If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.
Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.
If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	fluid
Colour	yellow
Odour	orange
Odour threshold.	Not available.
pH.	Not available.
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation Rate	Not applicable.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not applicable.
Relative density.	1,230 Kg/l
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not applicable.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

Information not available.

SECTION 10. Stability and reactivity.

10.1. Reactivity.

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid.

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

Information not available.

SECTION 11. Toxicological information.

11.1. Information on toxicological effects.

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.
This product contains sensitizing substance/s and may cause allergic reactions.

CRISTOBALITE
LD50 (Oral).> 2000 mg/kg (OECD 401, rat, MSDS supplier)
LC50 (Inhalation).> 2,6 mg/l (OECD 403, rat, MSDS supplier)
Irritation/Corrosion
Skin irritation: Not irritating (MSDS supplier).
Eye irritation: Not irritating (MSDS supplier).
Sensitization: Not sensitizing (MSDS supplier).

Mutagenicity: No data available (MSDS supplier).
Carcinogenicity: No data available (MSDS supplier).
Toxicity to reproduction: No data available (MSDS supplier).
STOT Repeated Exposure:
In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France).
In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. “There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk...” (SCOEL SUM Doc 94-final, June 2003).
There is a body of evidence supporting the fact that increased cancer risk would not be limited to people already suffering from silicosis. According to the current state of the art, worker protection against silicosis can be consistently assured by respecting the existing regulatory occupational exposure limits. Occupational exposure to nuisance dust (total and respirable) and respirable crystalline silica should be monitored and controlled.
“For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified (annex I, section 1.1.1.5, EC Regulation 1272/2008)".
Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product.
However, the actual levels of free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

SECTION 12. Ecological information.

12.1. Toxicity.

D-LIMONENE

LC50 - for Fish.	< 1 mg/l/96h (similar or equivalent to OECD 203, Pimephales promelas, freshwater, ECHA dossier).
EC50 - for Crustacea.	< 1 mg/l/48h (OECD 202, Daphnia magna, static, freshwater, ECHA dossier).

12.2. Persistence and degradability.

D-LIMONENE

Rapidly biodegradable.

CRISTOBALITE
NOT rapidly biodegradable.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information.

14.1. UN number.

Not applicable.

14.2. UN proper shipping name.

Not applicable.

14.3. Transport hazard class(es).

Not applicable.

14.4. Packing group.

Not applicable.

14.5. Environmental hazards.

Not applicable.

14.6. Special precautions for user.

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

Information not relevant.

SECTION 15. Regulatory information.

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

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product.
None.

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisarion (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

Information not available.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 3	Flammable liquid, category 3
STOT RE 1	Specific target organ toxicity - repeated exposure, category 1
Asp. Tox. 1	Aspiration hazard, category 1
Skin Irrit. 2	Skin irritation, category 2
Skin Sens. 1	Skin sensitization, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
H226	Flammable liquid and vapour.
H372	Causes damage to organs through prolonged or repeated exposure.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY
1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament

5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology

- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- ECHA website

Note for users:
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.

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 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.

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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