

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 DURATEMP EASY FIX

Publication date : 04.04.2018
Version : 01

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Section 1: Identification of the substance/mixture and of the company

1.1 Product Identifier

Substances : paraffin waxes
Index-no. : not applicable
EG-no. : 232-315-6
CAS-no. : 8002-74-2
REACH-registration no. : The substance does not require registration according to regulation (EC) no. 1907/2006 (REACH)
Other means or identification : hydrocarbones

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

Relevant identified uses : to be used in dental labs exclusively
Uses advised against : should not be used by untrained personnel

1.3 Details of the supplier of the safety data sheet

Manufacturer
ERK DENTAL MEDİKAL TIBBİ MALZ.TUR.SAN.VE TIC.LTD.ŞTİ
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)

Section 2: Hazards identification:

2.1 Classification of the substance or mixture:

Classification according to regulation (EC) no. 1272/2008 (CLP)

This substance does not meet the criteria for classification according to regulation (EC) no. 1272/2008 (CLP).

2.2 Label Elements

Labelling according to regulation (EC) no. 1272/2008 (CLP/GHS)

Hazard pictograms : NONE
Signal word : NONE

Hazardous component(s) for labelling:

Hazard statements : NONE

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Precautionary statements:

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P262 Do not get in eyes, on skin, or on clothing.
P370+ In case of fire:
P378 Use foam, carbon dioxide, dry powder to extinguish.

Supplemental Hazard information (EU):
NONE

2.3 Other Hazards:

Results of PBT and vPvP assessment:
PBT not applicable
vPvP not applicable

Section 3: Composition/information on ingredients

3.1 Substances

Principal component of the substance:

Substance name : paraffin
Index-no. : void
EG-no. : 232-315-6
CAS-no. : 8002-74-2

Impurities, stabilizers : none

Substance name :
Index-no. :
EG-no. :
CAS-no. :

3.2 Mixtures none

Description of the mixture:

EG-no.:
CAS-no. :
Index-Nno.:
REACH-registration no.:
Content ration: %
Classification according to regulation (EC) no. 1272/2008 (CLP)
none

(Full text of H- and EUH-phrases: see SECTION 16)

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Section 4: First aid measures

4.1 Description of first aid measures:

Following inhalation: Pure wax resp. wax not containing any kind of oil is showing almost no vapour pressure when fluid, for that an inhalative absorption of any toxicologically concerned component can be excluded.

Following skin contact: Contact with molten/fluid product may lead to burns. Cool down with cold water immediately, if necessary treat wound in a sterile manner, seek for medical advice. Any absorption of paraffin components by means of skin while the wax is solid cannot be expected.

Following eye contact: Rinse thoroughly with water, if necessary seek medical advice (when wax is hot/fluid)

Following ingestion: Rinse mouth – no further measures necessary.

Waxes can be applied as components of pharmaceuticals or food for this reason the question of absorption in the digestive tract after accidental ingestion is irrelevant.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: none Effects: none

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor: none Special treatment: none

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable: Foam, dry powder, carbon dioxide, water mist spray

Unsuitable: Water jet

5.2 Special hazards arising from the substance or mixture

In case of fire fumes are possible: carbon monoxide (CO).

5.3 Advice for fire-fighters

Respiratory protection independent of ambient environment – in case of fumes.

5.4 Additional indication:

Fire class: B Liquid substances or substances becoming liquid.

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Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Protective equipment:

Emergency procedures:

Avoid contact with skin, eyes and clothes when substance is hot and fluid.

For emergency responders

Personal protective equipment: see section 5.3

Avoid contact with skin, eyes and clothes when substance is hot and fluid.

3ff, 02-4ff, 02-5ff, 06-1ff, ZH02-ff,

6.2 Environmental precautions

No special precautions need to be taken.

6.3 Methods and material for containment and cleaning up

Let material solidify – clean up mechanically.

6.4 Reference to other sections

More information on disposal see section 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

Fire preventions: No special precautions necessary. Regular preventive fire protection.

Aerosol and dust generation preventions: Avoid generation of dust – work under fume hood.

Environmental precautions: No special precautions necessary.

Advice on general occupational hygiene: Observe general hygiene rules.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep containers tightly closed and store cool, dry and well ventilated. Keep away from sun rays. Best at 5 – 30 °C.

Requirements for storage rooms and vessels

Store in original bundles. Room temperature see above.

Storage class: 11 (TRGS 510) Materials to avoid: n.a.

7.3 Specific end uses

Sector specific guidelines: dental laboratories

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Section 8: Exposure controls / personal protection

8.1 Control parameters

Occupational exposure limits

Substance : paraffin
CAS-no. : 8002-74-2
Specification : Does not contain any substances - according to the common EU lists – that have to be monitored at work-places.
Limit value type (country of origin) : n.a.
Peak limitation : n.a.
Toxic to reproduction : n.a.
Source (TRGS) : n.a.

8.1.2 DNEL- and PNEC- values none

Substance: ;
CAS-Nr. :
Specification :
Value:

8.1.3 Control-Banding (e.g. ILO, EMKG) none

8.2 Exposure controls The type and extent of usage determine the choice of protective measures.

Appropriate engineering controls Provide good ventilation
Personal protective equipment

Eye / face protection

Safety glasses – not necessary if used according to the intended purpose.

Skin protection

Hand protection

in full contact : use appropriate safety gloves
material : polychloroprene - CR (0,5 mm), nitrile rubber - NBR (0,35 mm)
layer thickness (mm) : see above penetration time (min.): 8 hours
Splash contact : use appropriate safety gloves
material : polychloroprene - CR (0,5 mm), nitrile rubber - NBR (0,35 mm)
layer thickness (mm) : see above penetration time (min.): 8 hours

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Body protection

Appropriate

Respiratory protection

Not required under normal use.

Thermal hazards

Not required under normal use.

Environmental exposure controls

Do not allow to get into sewer system, surface or ground water.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Physical state	:	
- Aggregate state	:	Solid, waxes in different shapes and colours
- colour	:	various
Odour	:	Characteristic, different according to type
Odour threshold	:	No information available
pH-value	:	n.a.
Freezing point	:	< 50°C
Initial boiling point/boiling range	:	n.a.
Flash point	:	> 130°C
Evaporation rate	:	n.a.
Flammability	:	The substance is flammable, but does not intensify fires.
Upper/lower explosive limits	:	none
Vapour pressure	:	n.a.
Vapour density	:	n.a.
Relative density	:	ca. 0,93 g/cm ³
Solubility	:	Not soluble in water
Partition coefficient	:	n.a.
n-octanol/water	:	
Auto-ignition temperature	:	n.a.
Decomposition temperature	:	n.a.
Viscosity	:	n.a.
explosive properties	:	none
Oxidising properties	:	none

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9.2 Other information

No further information available
Physical hazards
Explosives

Section 10: Stability and reactivity

- 10.1 Reactivity:** no known unusual reactivity
- 10.2 Chemical stability:** stable under regular conditions.
- 10.3 Possibility of hazardous reactions:** no known hazardous reactions
- 10.4 Conditions to avoid:** not designated
- 10.5 Incompatible materials:** not designated
- 10.6 Hazardous decomposition products:** carbon monoxide, carbon dioxide

Section 11: Toxicological information

11.1 Information on toxicological effects

When used appropriately no dangers to health are currently known

Acute toxicity

No information available on systemic effects.

Skin irritation

Danger of burns when handling hot and liquid waxes.

Eye irritation

May harm when working with hot and liquid waxes.

Sensitisation to the respiratory tract / skin

Vapors have a very weak irritant effect.

Germ cell mutagenicity

No information available

Carcinogenicity

An extensive programme already realized in 1958 for clarifying the absence of carcinogenic properties in pure waxes was followed by the admission as food ingredient.

Reproductive toxicity

No information available

Specific target organ toxicity (single exposure) none

Specific target organ toxicity (repeated exposure) none

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Aspiration hazard
No information available

Symptoms related to the physical, chemical and toxicological characteristics:

In case of ingestion : may have a laxative effect
In case of skin contact : may cause burns when wax hot and liquid
In case of inhalation : seems impossible
In case of eye contact : seek for medical advice when eye contact with hot and liquid wax

Section 12: Ecological information

12.1 Toxicity
No information available

12.2 Persistence and degradability
No data available. As to consistency and non-solubility a bioavailability is very unlikely.

12.3 Bioaccumulative potential
Not significantly accumulative in living organisms.

12.4 Mobility in soil
No data available.

12.5 Results of PBT- and vPvB assessment
Not applicable.

12.6 Other adverse effects
None

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Section 13: Disposal considerations

13.1 Waste treatment methods

Contaminated packaging disposal
Recycle according to official regulations.

Waste codes / waste designations according to EWC / AVV:
No waste codes applicable.

Special precautions
None

Other relevant provisions for waste treatment national or EC
Dispose of waste according to applicable legislation

Section 14: Transport information

14.1 UN-no.
Not applicable

14.2 UN proper shipping name
ADR/RID
The product is not defined under ADR/RID regulations.
IMDG-Code / ICAO-TI / IATA-DGR
The product is not defined under IMDG regulations.

14.3 Transport hazard class(es) / hazard labels
Not relevant

14.4 Packing group
Not relevant

14.5 Environmental hazards
Environmentally hazardous substance marking
ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: yes / XXX no
Marine Pollutant: yes / XXX no

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14.6 Special precautions for user
No additional information available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Pollution category (X, Y or Z) : not applicable Type of ship (1, 2 or 3) : not applicable

Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
EU-regulations, e.g.:

Directive /EC) no. 2037/2000 (substances that deplete the ozone layer): not listed
Directive (EC) no. 850/2004 (persistent organic pollutants): not listed
Directive (EC) no. 689/2008 (Import and export of dangerous chemicals): not listed
Directive (EC) no. 648/2004 (Detergents Regulation): not listed
National regulations, e.g.:
Water hazard class (VwVws) : not water pollutant / registration no. 268

Technical instructions on Air Quality Control (TA-Luft): not applicable
Other relevant regulations: TRGS 500, 510 (Germany): storage class: 11 (flammable solids)

15.2 Chemical safety assessment
For this product a chemical safety assessment was not carried out.

Section 16: Other information

Indication of changes
Regulation (EC) no. 1272/2008 (CLP, EU_GHS) Section1: Emergency number, editorial revision

Abbreviations and acronyms
n.a. Not applicable
Key literature references and sources for data
Gestis Stoffdatenbank - <http://gestis.itrust.de/> Authority for chemicals www.baua.de

Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:
No classification

Relevant R-, H- and EUH-phrases (number and full text):
None of the above stated phrases is relevant. P-phrases stated in section 2.2
Training advice
Not applicable for qualified dental technicians.

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Further information
none

This information is based on our present state of knowledge. It should therefore not be construed as guaranteeing specific properties of the products described or their suitability for a particular application. We do not take any responsibility for possible sources of errors or sufficiency of this document. The user of the product accepts the sole responsibility to adhere to all herein mentioned regulations. It is the user's obligation to read this document carefully.

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.

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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