

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 DURAVEX INVEX LIQUID

Publication date : 24.08.2022
Version : 01

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER

1.1 Product identifier:-

Product name : Duradent Duravex Invex Liquid

1.2 Other means of identification:-

Not applicable.

1.3 Recommended use of the chemical and restrictions on use:-

Not applicable.

Identified uses : Discharging agent.

1.4 Details of the manufacturer and importer:-

Manufacturer : ERK DENTAL MEDİKAL TIBBİ MALZ.TUR.SAN.VE TIC.LTD.STİ
TUNA MAH. SANAT CAD. NO 17 D:211
Bornova/İzmir Türkiye

1.5 Emergency phone number : +90 232 458 20 55
(Mon. - Fri.: 8:00/13:00 - 13.30/18:00)

2. HAZARD(S) IDENTIFICATION

2.1 GHS Classification:-

Acute Tox. 4 H302 Harmful if swallowed.

Acute Tox. 4 H312 Harmful in contact with skin. Eye Irrit. 2 H319 Causes serious eye irritation.

2.2 GHS Label elements, including precautionary statements:-

Hazard Pictogram:



GHS07

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Signal word : Warning

Hazard-determining components

of labelling : Hydrofluoric acid

Hazard statements : H302+H312 Harmful if swallowed or in contact with skin. H319 Causes serious eye irritation.

Precautionary statements : P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P322 Specific measures (see on this label).

P312 Call a POISON CENTER/doctor if you feel unwell. P363 Wash contaminated clothing before reuse.

P302+P352 IF ON SKIN: Wash with plenty of soap and water

Additional information : EUH066 Repeated exposure may cause skin dryness or cracking.

2.3 Other hazards:-

Special safety notes for the use of IPS Ceramic Etching Gel: Hydrofluoric acid is highly toxic. It is strongly corrosive and does not cause any warning pain on the surface of skin and mucous membranes, but causes subsequent, painful in-depth effect.

Results of PBT and vPvB assessment: PBT :Not applicable.

vPvB : Not applicable.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient name	CAS No.	Classification	Concentration
Sulphuric acid	7664-93-9	Skin Corr. 1A - H314	1-<2.5%
Hydrofluoric acid	7664-39-3	Acute Tox. 2 - H300	0.3-<1%
		Acute Tox. 1 - H310	
		Acute Tox. 2 - H330	
		Skin Corr. 1A - H314	
Non-hazardous ingredients	N/A	N/A	to 100%

For the full text of the H-Statements mentioned in this Section, refer to Section 16.

4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-

General advice:	Remove contaminated clothing and shoes immediately and launder thoroughly before reusing. First aid facilities include first aid rooms and medical centres. If a risk assessment determines that a first aid room or medical centre is not needed, a rest area within the workplace may be suitable to assist an injured or ill person.
If inhaled:	Ensure supply of fresh air. Remove affected person from the immediate area. Keep patient warm. Consult doctor if symptoms persist. In case of unconsciousness place patient stably in side position for transportation.
In case of skin contact:	Wash off immediately with water and soap and rinse thoroughly. Rub in Ca-gluconate solution or Ca-gluconate gel immediately. Seek medical attention.
In case of eye contact:	Remove contact lenses, irrigate copiously with clean, fresh water for at least 15 minutes holding the eyelids apart and seek medical advice.
If swallowed:	Do not induce vomiting. Rinse mouth thoroughly with water. Let plenty of water be drunk in small gulps. Never give anything by mouth to an unconscious person. Call a doctor immediately.

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4.2 Symptoms caused by exposure:

Please refer to section 2.2 and section 11.

4.3 Medical attention and special treatment :

Antidote: Ca-gluconate solution / Ca-gluconate gel.

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing equipment:

Suitable extinguishing media

: This product is not flammable.

Use dire extinguishing methods suitable to surrounding conditions.

Unsuitable extinguishing media

: No further relevant information available.

5.2 Specific hazards arising from the substance/mixture/product:

During heating or in case of fire poisonous gases are produced. Special protective equipment and precautions for fire fighters:-

Special personal protective equipment

: Wear self-contained respiratory protective device.

Precautions

: Cool endangered receptacles with water spray.

Hazchem code

: No further relevant information available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:-

Wear protective equipment. Keep unprotected persons away.

Use of suitable equipment (incl PPE) to prevent contamination of skin, eyes, clothing, removal of ignition sources, ventilation, emergency procedures (eg. evacuate, consult expert).

6.2 Environmental precautions:-

Do not allow to enter sewers/surface or ground water.

6.3 Methods and materials for containment and cleaning up:-

Use neutralising agent.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents.

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7. HANDLING AND STORAGE

7.1 Precautions for safe handling:

No special measures necessary if stored and handled as prescribed.

Only adequately trained personnel should handle this product – for use in dentistry only. Open and handle receptacle with care.

Ensure good ventilation/exhaustion at the workplace. Keep ignition sources away – do not smoke.

Protect against electrostatic charges. Wash hands before breaks and after work.

Do not eat, drink or smoke during work time. Remove soiled or soaked clothing immediately. Keep away from foodstuffs and beverages.

7.2 Conditions for safe storage, including any incompatibilities:

Keep only in the original container.

Attacks materials containing glass and silicate.

Containers which are opened must be carefully closed and kept upright to prevent leakage. Keep container tightly sealed.

Store in cool, dry conditions in well-sealed receptacles. Store receptacle in a well ventilated area.

Recommended storage temperature for storage rooms and vessels is 20 - 30°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:- Occupational exposure limits:

Component	CAS No.	Value	Parameters	Basis
Sulphuric acid Hydrofluoric acid	7664-93-9 7664-39-3	Long-term value: 0.05* mg/m ³ *mist – is defined as fraction. Short-term value: 2.5 mg/m ³ Long-term value: 1.5 mg/m ³	3 ppm 1.8 ppm	The lists valid during the making were used as basis.

Ingredients with biological limit values:

Exposure should be kept to as low as practicable and below the AOES.

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8.2 Biological monitoring:

Assess in accordance with exposure limits – please refer to section 8.1.

Exposure controls / Personal protective equipment / General protective and hygienic measures:

Usual hygienic measures for dental practice. Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing. Avoid contact with the eyes and skin.

Do not inhale gases / fumes / aerosols.

8.3 Control banding:

Use good industrial hygiene practice and general ventilation.

8.4 Engineering controls:

In case of intensive contact, wear protective gloves (EN 374).

Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties).

Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves.

Protective gloves shall be replaced immediately when physically damaged or worn.

8.5 Individual protection measures include PPE:

Eye/face protection:

Safety glasses

Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.



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Skin protection



: Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. Material of gloves

Butyl rubber, BR. Fluorocarbon rubber (Viton). PVA gloves.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection

: Provide for good ventilation of working area (local exhaust ventilation, if necessary).

In case of brief exposure or low pollution use respiratory filter device.

In case of intensive or longer exposure use self-contained respiratory protective device.

Recommended filter device for short term use:

Combination filter E-P2.

9. PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on physical/chemical properties:-

- | | |
|--|---|
| a) Appearance/Form | : Fluid. |
| b) Colour | : Colourless. |
| c) Odour | : Odourless. |
| d) Odour threshold | : Not determined. |
| e) pH value at 20°C | : 2.2 (ISO 787) |
| f) Melting point/melting range | : Undetermined. |
| g) Boiling point/boiling range | : ~100°C. |
| h) Flash point | : Undetermined. |
| i) Ignition temperature | : Not applicable. |
| j) Self-igniting | : Product is not self-igniting. |
| k) Danger of explosion | : Product does not present an explosion hazard. |
| l) Upper/lower flammability or explosive limits: | Lower Not determined. Upper Not determined. |

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Vapour pressure	: Not determined.
m) Density at 20oC	: ~1.008 g/cm ³ .
n) Relative density	: Not determined.
o) Vapour density	: Not determined.
p) Evaporation rate	: Not determined.
q) Solubility in/miscibility with water	: Fully miscible.
r) Partition coefficient: n- octanol/water	: Not determined.
s) Viscosity	: Dynamic Not determined. Kinematic Not determined

10. STABILITY AND REACTIVITY

10.1 Reactivity:-

No further relevant information available.

10.2 Chemical stability:-

Stable under normal handling and storage conditions. Thermal decomposition / conditions to be avoided; No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions:-

Reacts with: Ammonia Sulphuric acid

Reacts with alkali (lyes).

Reacts with organic substances. Reacts with metals forming hydrogen.

10.4 Conditions to avoid:-

Keep away from heat and direct sunlight.

10.5 Incompatible materials:-

Attacks materials containing glass and silicate.

10.6 Hazardous decomposition products:-

None under normal conditions of storage and use.

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11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-

Acute toxicity / Values relevant for classification:
No further relevant information available.

Skin corrosion/irritation	: No irritant effect.
Serious eye damage/eye irritation	: Irritating effect.
Respiratory or skin sensitization	: No sensitizing effects known.
Germ cell mutagenicity	: No further relevant information available.
Carcinogenicity	: No further relevant information available.
Reproductive toxicity	: No further relevant information available.
Specific target organ toxicity - single exposure	: No further relevant information available.
Specific target organ toxicity - repeated exposure	: No further relevant information available.
Aspiration hazard	: No further relevant information available.
Additional information	: No further relevant information available.

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure	: No further relevant information available.
Swallowed	: No further relevant information available.
Eyes	: Irritating effect.
Skin	: No further relevant information available.
Inhaled	: No further relevant information available.
Long Term (Chronic) Exposure	: No further relevant information available.
Swallowed	: No further relevant information available.
Eyes	: Irritating effect.
Skin	: No further relevant information available.
Inhaled	: No further relevant information available.

11.3 Early onset symptoms related to exposure:-

No further relevant information available.

11.4 Delayed health effects from exposure:-

No further relevant information available.

11.5 Exposure levels and health effects:-

No further relevant information available.

11.6 Interactive effects:-

No further relevant information available.

11.7 Other:- No further relevant information available.

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12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:-

No further relevant information available.

12.2 Persistence/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.

12.5 Other adverse effects:-

No further relevant information available.

Additional ecological information / General notes:

Generally not hazardous in water.

Do not allow undiluted product or large quantities if it to reach ground water, water course or sewage system.

12.6 Other adverse effects:-

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:-

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal.

Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

Disposal must be made according to official regulations.

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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14. TRANSPORT INFORMATION

UN number ADR / IMDG / IATA	: Void.
UN proper shipping name or technical name:-	
ADR	: Void.
IMDG, IATA	: Void.
Transport hazard class(es)	: Void.
Label	: Void.
Packaging group	: Void.
Environmental hazards	: Not applicable.
Special precautions for user	: Not applicable.
Danger code	: Not applicable.
EMS Number	: Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:	Not applicable.
Additional information – ADR	: Not applicable.
Additional information – IMDG	: Not applicable.
Transport /Additional information	: Product is not classified as a dangerous good for transport.
Hazchem or emergency action code	: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.

Standard for the Uniform Scheduling of Medicines and Poisons.

Carcinogen classification under WHS Regulation 2011, Schedule 10.

Notification status in accordance with section 3 and current national legislation.

HSNO Approval : HSR001588, HSR001569

EPA NZ Classes of hazardous properties:

Classification 6.1D (All) Substances that are acutely toxic - Harmful

Classification 6.1E (All) Substances that are acutely toxic – May be harmful, aspiration hazard

Classification 6.3A Substances that are irritating to the skin

Classification 6.4A Substances that are mildly irritating to the skin

Classification 8.1A Substances that are corrosive to metals

Classification 9.1D (All) Substances that are slightly harmful to the aquatic environment or are otherwise designed for biocidal action

Classification 9.3B Substances that are ecotoxic to terrestrial vertebrates

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16. OTHER INFORMATION

Key to abbreviations SDS:- /acronyms used in
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H330 Fatal if inhaled.

Key literature references/data sources used to compile SDS:-

Standard EN420:2003 General requirements for protective gloves: disposable gloves, e.g. nitrile rubber, material thickness 0.1 mm (Australian Standard 2161).
Long-term exposure (Level 6: < 480 min): protective gloves, e.g. nitrile rubber, material thickness 0.7 mm (Australian Standard 2161).
Personal eye protection - Eye and face protectors for occupational applications: safety glasses (Australian Standard AS 1336 and AS/NZS 1337.1:2010).

Copyright statement:-

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Abbreviations and acronyms:-

ADR : Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road).
IMDG : International Maritime Code for Dangerous Goods.
IATA : International Air Transport Association.
GHS : Globally Harmonised System of Classification and Labelling 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).
LC50 : Lethal concentration, 50 percent.
LD50 : Lethal dose, 50 percent.
Flam. Liq. 2 : Flammable liquids, Hazard Category 2.
Flam. Liq. 3 : Flammable liquids, Hazard Category 3.
Acute Tox. 4 : Acute toxicity, Hazard Category 4.
Skin Irrit. 2 : Skin corrosion/irritation, Hazard Category 2.
Eye Irrit. 2 : Serious eye damage/eye irritation, Hazard Category 2.
Repr. 2 : Reproductive toxicity, Hazard Category 2.
STOT SE 3 : Specific target organ toxicity - Single exposure, Hazard Category 3.
STOT RE 2 : Specific target organ toxicity - Repeated exposure, Hazard Category 2.
Asp. Tox. 1 : Aspiration hazard, Hazard Category 1.

* Data compared to the previous version altered

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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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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