

# Safety data sheet



according to Regulation (EC) 1907/2006

Date of issue: 19 October 2010

print date: 19 October 2010

## 1. Identification of the substance/preparation and of the company

### Identification of the product:

Product name: File Care®  
Use of the substance/preparation: Lubricant for root canal

### Manufacturer/supplier identification:

Company: VDW GmbH  
Bayerwaldstr.15, D-81737 München, Germany Tel: ++49 89 62734-0  
e-mail: info@vdw-dental.com  
Contact for information: Quality Management  
Telephone: ++49 89 62734- 0 • Telefax: ++49 89 62734-340  
Emergency Call: Giftnotruf: Klinikum Rechts der Isar München Telephone: ++49 89-19240

## 2. Hazard Identification

File Care® is a medical product according Directive 93/42/EC and no hazardous substance or preparation according Regulation 1272/2008 EC.

## 3. Composition / information on ingredients

Preparation of following substances and not hazardous substances as specified in Directive 1272/2008 EC

Name according Regulation EC:	CAS-No.	EG-No.	Risk symbols	R-Phrases	Content
Carbamide peroxide	124-43-6	204-701-4	Xi	37/38, 41	5-15%
Ethylenediamine-tetraacetic acid	60-00-4	200-449-4	Xi	36	10-20%

## 4. First aid measures

After inhalation: fresh air. If feeling unwell contact doctor  
After skin contact: wash off with plenty of water  
After eye contact: rinse out 15 min. with plenty of water with the eyelid held wide open. Consult doctor.  
After swallowing: if victim is still conscious, make him drink plenty of water, Consult doctor if feeling unwell.

## 5. Fire-fighting measures

Suitable extinguishing media: CO<sub>2</sub>, water, foam, powder

Special risks: In event of fire formation of hazardous combustion gases or vapours possible

## 6. Accidental release measures

### Procedures for cleaning / absorption:

Take up with liquid-absorbent material. Forward for disposal. Clean up affected area

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## 7. Handling and storage

**Handling:** Avoid contact with eyes, skin and clothes.  
**Storage:** Tightly closed at a dark and dry place. Best storage temperature 2-12°C

## 8. Exposure controls / personal protection

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier

Respiratory protection: not necessary  
Eye protection: required (EN 166)  
Hand protection: in full contact: Glove material: latex or nitrile  
Layer thickness: 0,4 mm  
Breakthrough time: > 480 min

### Additional reference:

The data are based on own examinations, literature data and information from glove manufacturers or are derived by analogy reasoning from similar materials.

It is to be noted that the daily life of a chemical protection glove can be clearly shorter in practice because of the many factors of influence (e.g. temperature, stretch etc.) than the permeation time determined after EN 374.

### Industrial hygiene:

Change contaminated clothing. Wash hands and face after working with substance.  
Under no circumstances eat or drink at workplace

## 9. Physical and chemical properties

Form:		pasty
Colour:		white
Odour:		characteristic
Flash point:		not available
Ignition temperature:		not available
Vapour pressure:	(20°C)	not available
Viscosity:	(20°C)	600000-1300000 cps
Solubility in water	(20°C)	slightly soluble
pH-value		2,7 – 3,2

## 10. Stability and reactivity

### Hazardous decomposition products:

no information available

### Hazardous reactions:

No dangerous reactions known

### Conditions to be avoided:

Temperature > 50°

### Substances to be avoided

alkali, metals and oxidizing materials

### Hazardous decomposition products:

Nitrous gases (NO<sub>x</sub>), ammonia, carbon monoxide, carbon dioxide

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## 11. Toxicological information

### Acute toxicity:

Carbamide peroxide: LD<sub>50</sub> (oral, rat) > 2000 mg/kg  
Ethylenediamine-tetraacetic acid: LD<sub>50</sub> (oral, rat) 2580 mg/kg

### Further toxicologic information

After eye contact: irritation  
After skin contact: irritation if skin is delicate

### Further data:

The product should be handled with the care usual when dealing with chemicals

## 12. Ecological information

### Ecotoxic effects:

Quantitative data on the ecological effect of this product are not available

### Further ecologic data:

No ecological problems are to be expected when the product is handled and used with due care and attention

## 13. Disposal considerations

Contact a licensed professional waste disposal service to dispose of this material.  
Observe all federal, state and local environmental regulations

## 14. Transport information

Not subject to transport regulations

The transport regulations are cited according to international regulations and in form applicable in Germany.  
Possible national deviations in other countries are not considered

## 15. Regulatory information

### Labelling according to EC Directives:

No hazardous product as specified in Directive 67/548/EEC

Symbol: -

R-phrases: -

S-phrases: -

## 16. Other information

Revised version

This Safety Data sheet is corresponding to the GHS (Globally Harmonized System of Classification and Labelling of chemicals)

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.

VDW GmbH shall not be held liable for any damage resulting from handling or from contact with the above product

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions.

It does not represent a guarantee of the properties of the product.