according to Regulation (EC) No 1907/2006

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

1.1. Product identifier

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

Use of the substance/mixture

Relining material for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Company name:

ProTech Professional Products, Inc.

Street:

2900 NW Commerce Park Dr. Suote 10

Place:

Boynton Beach, FL 33426

Telephone:

561/493-9818

fax: 561/493-9825

e-mail: Internet: protechdental@bellsouth.net www.dentallabproducts.com

1.4. Emergency telephone

Infotrac: 800/535-5053

number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Hazard categories:

Respiratory or skin sensitisation: Skin Sens. 1

Hazard Statements:

May cause an allergic skin reaction.

2.2. Label elements

Hazardous components which must be listed on the label

"dibenzoyl peroxide; benzoyl peroxide"

Signal word:

Warning

Pictograms:



Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container to according to local and applicable legislation of dispose

of waste.

2.3. Other hazards

No information available.

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Contains: polydimethylsiloxane + inert filler and pigment + part of organic peroxide

Hazardous components

| CAS No | Chemical name | | | | |
|---------|---|--------------|----------|--|--|
| | EC No | Index No | REACH No | | |
| | Classification according to Regulation (EC) No. 1272/2008 [CLP] | | | | |
| 94-36-0 | "dibenzoyl peroxide; benzoyl peroxide" | | | | |
| | 202-327-6 | 617-008-00-0 | | | |
| | Org. Perox. B, Eye Irrit. 2, Skin Sens. 1, Aquatic Acute 1 (M-Factor = 10); H241 H319 H317 H400 | | | | |

Full text of H and EUH phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water.

Do not induce vomiting. If you feel unwell, seek medical advice.

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

No information available.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes

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and clothes. Use personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary. Clean contaminated objects and areas thoroughly observing environmental regulations.

6.3. Methods and material for containment and cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No special measures are necessary.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Advice on storage compatibility

Do not store with combustible materials. Do not store with spontaneous flammable materials.

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

7.3. Specific end use(s)

Silicone material for denture relinings.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

| CAS No | Substance | ppm | mg/m³ | fibres/ml | Category | Origin |
|---------|--------------------|-----|-------|-----------|---------------|--------|
| 94-36-0 | Dibenzoyl peroxide | - | 5 | | TWA (8 h) | WEL |
| | | - | - | | STEL (15 min) | WEL |

8.2. Exposure controls

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary . When using do not eat or drink.

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including

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the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Suitable are gloves of the following material: NR (natural rubber, natural latex), CR (polychloroprene, chloroprene rubber), NBR (Nitrile rubber), Butyl caoutchouc (butyl rubber), FKM (fluoro rubber), PVC (Polyvinyl chloride)

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Paste

Colour:

gingiva coloured

Odour:

odourless

Test method

pH-Value:

not determined

Changes in the physical state

Melting point:

not determined

Initial boiling point and boiling range:

not determined

Flash point:

>100 °C DIN 51755

Flammability

Solid: Gas:

not determined

not applicable

Lower explosion limits:

Upper explosion limits:

not determined

not determined >200 °C DIN 51794

Ignition temperature:

Auto-ignition temperature

Solid:

not determined not applicable

Decomposition temperature:

>250 °C

Oxidizing properties

Not oxidizing.

Vapour pressure:

(at 20 °C)

<1 hPa

Density (at 20 °C):

1,1 g/cm3 DIN 51757

Water solubility:

insoluble

Solubility in other solvents

not determined

Partition coefficient:

not determined

Vapour density:

not determined

Evaporation rate:

not determined

9.2. Other information

according to Regulation (EC) No 1907/2006

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Solid content:

not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with: combustible materials.

10.4. Conditions to avoid

Tthe material may autopolymerise at a temperature exceeding 60°C/ 140°F. Therefore keep containers tightly closed in a refrigerator at 2°C-12°C/ 36°F-54°F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

At a temperature of approx. 150°C/302°F a small amount of formaldehyde can be released by oxidative degradation.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

| CAS No | Chemical name | | | | | | | |
|---------|--|--------|-------------|---------|----------|--|--|--|
| | Exposure routes | Method | Dose | Species | Source | | | |
| 94-36-0 | "dibenzoyl peroxide; benzoyl peroxide" | | | | | | | |
| | oral | LD50 | >5000 mg/kg | Rat | | | | |
| | inhalative (4 h) aerosol | LC50 | 24,3 mg/l | Rat | OECD 403 | | | |

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. ("dibenzoyl peroxide; benzoyl peroxide")

STOT-single exposure

Based on available data, the classification criteria are not met.

Severe effects after repeated or prolonged exposure

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

SECTION 12: Ecological information

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12.1. Toxicity

The product is not: Ecotoxic.

| CAS No | Chemical name | | | | | | | |
|---------|--|-----------|-----------|-----------|--|----------|--|--|
| | Aquatic toxicity | Method | Dose | [h] [d] | Species | Source | | |
| 94-36-0 | "dibenzoyl peroxide; benzoyl peroxide" | | | | | | | |
| | Acute fish toxicity | LC50 | 0,06 mg/l | 96 h | Oncorhynchus mykiss (Rainbow trout) | OECD 203 | | |
| | Acute algae toxicity | ErC50 | 0,07 mg/l | | Pseudokirchneriella subcapitata | OECD 201 | | |
| | Acute crustacea toxicity | EC50 | 0,11 mg/l | 48 h | Daphnia magna (Big water flea) | OECD 202 | | |
| | Acute bacteria toxicity | (35 mg/l) |) | 0,5 h | | OECD 209 | | |

12.2. Persistence and degradability

The product has not been tested.

| CAS No | Chemical name | | | | | | |
|---------|--|-------|----|--------|--|--|--|
| | Method | Value | d | Source | | | |
| | Evaluation | | | | | | |
| 94-36-0 | "dibenzoyl peroxide; benzoyl peroxide" | | | | | | |
| | OECD 301D/ EEC 92/69/V, C.4-E | 68% | 28 | | | | |
| | Biodegradable. | | | | | | |

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identivied as PBT/ vPvB substances

12.6. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

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| 14.1. UN number: | No dangerous good in sense of this transport regulation. | | | | |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. | | | | |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. | | | | |

No dangerous good in sense of this transport regulation.

14.4. Packing group:

Marine transport (IMDG)

14.1_UN number:

No dangerous good in sense of this transport regulation.

14.2_UN proper shipping name:

No dangerous good in sense of this transport regulation.

No dangerous good in sense of this transport regulation.

No dangerous good in sense of this transport regulation.

No dangerous good in sense of this transport regulation.

Air transport (ICAO)

14.1.UN number:No dangerous good in sense of this transport regulation.14.2.UN proper shipping name:No dangerous good in sense of this transport regulation.14.3.Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4.Packing group:No dangerous good in sense of this transport regulation.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

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

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

mixture EU regulatory information

Additional information

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

National regulatory information

Employment restrictions:

Observe employment restrictions for young people.

Water contaminating class (D):

- - not water contaminating

Skin resorption/Sensitization:

Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

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 Harmonized 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 LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Relevant H- and EUH-phrases (Number and full text)

H241 Heating may cause a fire or explosion. H317 May cause an allergic skin reaction.

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H319

Causes serious eye irritation.

H400

Very toxic to aquatic life.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)