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

DE Nanohybride composite, assorted colors

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

Use of the substance/mixture

for dental use only

1.3. Details of the supplier of the safety data sheet

DE Healthcare Ltd.

Unit 9, Kingsthorpe Business Centre,

Studland Road, Kingsthorpe,

Northampton NN2 6NE U.K.

E-Mail: info@dehpbrand.com Tel.: +44 1634 266 056

Distributed by/Distribudo por/Distribue par/Vertrieb durch/Distribuito da And in the USA/Y en EEUU/Et aux Etats-Unis/Und in USA/E in USA:

41 Weaver Road, Denver, PA 17517 USA

Emergency #: Chemtrec US (800) 424-9300 EU Tel.: 112

International: 001 703-527-3887 Suisse: 145

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC

Indications of danger: Xi - Irritant

R phrases:

May cause sensitisation by skin contact.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2 Respiratory/skin sensitization: Skin Sens. 1

Hazard Statements: Causes skin irritation.

May cause an allergic skin reaction. Causes serious eye irritation.

2.2. Label elements

Hazardous components which must be listed on the label

TEGDMA

Signal word: Warning Pictograms: GHS07



Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

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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.

P337+P313 If eye irritation persists: Get medical advice/attention.

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

P332+P313 If skin irritation occurs: Get medical advice/attention.

Additional advice on labelling

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

| EC No | Chemical name | Quantity |
|-----------|---|------------|
| CAS No | Classification according to Directive 67/548/EEC | |
| Index No | Classification according to Regulation (EC) No. 1272/2008 [CLP] | |
| REACH No | | |
| 216-367-7 | BISGMA | 5 - < 10 % |
| 1565-94-2 | Xi - Irritant R36/37/38 | |
| | Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335 | |
| 203-652-6 | TEGDMA | 5 - < 10 % |
| 109-16-0 | Xi - Irritant R36/37/38-43 | |
| | Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335 | |

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

SECTION 4: First aid measures

4.1. Description of first aid measures

After contact with skin

After contact with skin, wash immediately with: Water and soap.

After contact with eyes

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

After ingestion

Seek medical attention if problems persist.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.

Additional information

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.

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6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated areas thoroughly.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid contact with skin and eyes.

Restricted to professional users. Keep out of the reach of children.

Observe instructions for use.

Further information on handling

After use replace the closing cap immediately.

7.2. Conditions for safe storage, including any incompatibilities

Further information on storage conditions

Substances sensitive to light.

Recommended storage temperature: 4 - 23 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Protective and hygiene measures

When using do not eat, drink or smoke.

Eye/face protection

Framed glasses.

Hand protection

Single-use gloves.

Skin protection

Lab apron.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Paste Colour: off-white

Test method

Changes in the physical state

Density (at 23 °C): 2.2 g/cm3 Water solubility: insoluble (at 23 °C)

Solubility in other solvents

Ethanol. (partially soluble)

SECTION 10: Stability and reactivity

10.4. Conditions to avoid

Light.

UV-radiation/sunlight.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

| CAS No | Chemical name | | | | | | |
|----------|-----------------|--------|-------------|---------|------------------|--|--|
| | Exposure routes | Method | Dose | Species | Source | | |
| 109-16-0 | TEGDMA | | | | | | |
| | oral | LD50 | 10837 mg/kg | Rat | literature value | | |

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (TEGDMA)

SECTION 12: Ecological information

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water

| CAS No | Chemical name | Log Pow |
|-----------|---------------|---------|
| 1565-94-2 | BISGMA | 4.94 |
| 109-16-0 | TEGDMA | 1.88 |

Further information

According to the criteria of the EC-classification and labelling "dangerous for the environment" (93/21/EEC) the material/product is not to be classified as dangerous to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number:</u> ---

Inland waterways transport (ADN)

<u>14.1. UN number:</u> ---

Marine transport (IMDG)

<u>14.1. UN number:</u> ---

Air transport (ICAO)

<u>14.1. UN number:</u> ---

Other applicable information

Not a hazardous material with respect to these transportation regulations.

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SECTION 15: Regulatory information

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

National regulatory information

Additional information

SECTION 16: Other information

Relevant R-phrases (Number and full text)

36/37/38 Irritating to eyes, respiratory system and skin.
43 May cause sensitisation by skin contact.

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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.

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