According to regulation (EC) No. 453/2010 annex I

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SECTION 1- IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Revision date: 18/05/2015 Commercial name: DE TEMPORARY FILLING PLUS, white Product references: 9790866 & 9792600 Relevant use of mixture: Temporary filling cement

Information concerning safety data sheet supplier: DE Healthcare Ltd. Unit 9, Kingsthorpe Business Centre, Studland Road, Kingsthorpe, Northampton NN2 6NE U.K. Email: info@dehpbrand.com Emergency telephone number: CHEMTREC 001 703-527-3887

Téléphone : +44 1634 266 056

SECTION 2 – HAZARDS IDENTIFICATION

2.1 Classification of the mixture

2.1.1 Classification according to regulation (EC) N° 1272/2008 (CLP): Acute Tox. 4: H302; eye irrit. 2 : H319 ; Aquatic Acute 1 : H400; Aquatic Chronic 1 : H410

2.1.2 Classification according to the directive N° 67/548/CEE:

Xn, R22: harmful if swallowed, Xi : R36 : eye Dam. ; N: R51/53: dangerous for the environment

2.1.3 Additional Informations

The full text of the classes and categories of danger: hazards H and R phrases are mentioned in Section 16.

2.2 Label elements

Pictogram (s)

SGH 07: exclamation mark

SGH 09: Environment



Warning



Warning

Signal word

Hazard statements

- H302Harmful if swallowed, cat.4H 319Causes serious eye irritation, cat.2H400Very toxic to aquatic life, cat.1
- H410 Very toxic to aquatic life with long lasting effects, cat.1

Precautionary statement(s)

P273	Avoid release to the environment
P280	Wear protective gloves/protective clothing/eye protection/face protection
P305+351+338	IF IN EYES, rinse cautiously with water for several minutes, remove contact
	lenses if present and continue rinse continuously, in a gentle manner

2.3 Other hazards

Not available

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SECTION 3 – COMPOSITION /INFORMATION ON INGREDIENTS

Contains: zinc oxide and zinc sulfate

Index CE/CAS	Chemical name	Mass in %	According to directive N° 67/548/CEE (DPD)	According to regulation (CE) N° 1272/2008 (CLP)	Generic threshold
Index : 030-013-00-7 CE : 215-222-5 CAS : 1314-13-2	Zinc oxide	30-40	N : R50-53	Aquatic Acute 1 : H400 Aquatic Chronic 1 : H410	≥ 0,1 % ≥ 0,1 %
Index : 030-006-00-9 CE : 231-793-3 CAS : 7733-02-0	Zinc sulfate	10-20	Harmfull, Xn, ingest. : R22 Irritating Xi : R41 N : R50-53	Acute Tox. 4 : H302 Eye Dam. 1 : H318 Aquatic Acute 1 : H400 Aquatic Chronic 1 : H410	≥ 1 % ≥ 1 % ≥ 0,1 % ≥ 0,1 %

Note: The full text of hazard H and R-phrases is specified in section 16.

SECTION 4 - FIRST AID MEASURES

4.1 Description of the first aid measures

Inhalation	Remove to fresh air. Keep airway clear. In case of unconsciousness place patient stably in side position for transportation. Seek medical advice.
Contact with skin	Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, seek medical attention.
Contact with eyes	Irrigate copiously with clean, fresh water at least 15 minutes keeping the evelids opened. Seek medical advice.
Ingestion	Do not drink, do not induce vomiting, seek medical advice.
4.2 Most important symptoms and effects, both acute and delayed	Not available
4.3 Indications of possible immediate medical	Not available

of possible immediate medical attention and particular treatment needed

SECTION 5 - FIREFIGHTING MEASURES

5.1 Extinguishing media	
Suitable extinguishing media	All are suitable.
5.2 Special hazards resulting from substance or mixture	Avoid breathing vapors.
5.3 Advice to firefighters	Use self-contained breathing apparatus

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Individual precautions, protection equipment and emergency procedures

Basic precautions	Wear gloves and suitable goggles. Do not breathe vapors. Eliminate all ignition sources.
Means of protection	Consult section 8.
6.2 Environmental precautions	Do not dump into drains.

6.3 Methods and material of confinement and cleaning up

Absorb with an inert material (sand, vermiculite). Wash the soiled area with water.

6.4 References to other sections

Consult section 8 for personal protection Consult section 13 for disposal conditions

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SECTION 7 - HANDLING AND STORAGE

7.1 Precautions for safe handlin	g	
	Keep out of reach of children. Avoid contact with eyes.	
	Do not swallow. Do not breathe vapours. Close tightly the bottle after use.	
	Wash your hands thoroughly after handling.	
	Wash soiled clothing before reuse.	
	Comply with conditions of use.	
7.2 Conditions for safe storage, including any incompatibilities		
	Keep the product in its original pack, tightly closed and keep container dry.	
	Keep in a cool place at a temperature between 10 - 25°C.	
7.3 Special end use(s)	Product for professional dental use	
SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION		

8.1 Control parameters	Zinc oxide France/Belgium / Spain TLV : 10mg/m ³ Germany TLV 4 (inhalable aerosol) mg/m ³
Respiratory protection	Not necessary in normal use.
Hand protection	Wear appropriate gloves.
Eye/face protection	Wear protective goggles.
Skin and body protection	Wear safety clothing.
	Wash hands after use
	Do not eat, drink or smoke during use.

SECTION 9 - PHYSICAL & CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Paste
Color	White/Pink/Grey (according to the product reference)
Odour	None
PH	6-6.5
Relative density at 20°C	1.011

SECTION 10 – STABILITY & REACTIVITY

Reactivity	Not available
Chemical stability	Chemically stable under normal conditions of use.
Possibility of hazardous reactions	No hazardous reactions are foreseeable in normal condition of use and storage.
Conditions to avoid	Humidity, heat.
Incompatible materials	None
Hazardous decomposition products	Not available

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects11.2 Other informations

May cause sensitization by eye contact Not available

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	SECTION 12 – ECOLOGICAL INFORMATION
12.1 Toxicity	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
12.2 Persistence and degradability	Not available
12.3 Bioaccumulation potential	Not available
12.4 Mobility in the soil	Not available
12.5 Results of PBT and vPvB assessments	Not available
12.6 Other adverse effects	Not available
	SECTION 13 - DISPOSAL MEASURES
13.1 Waste treatment methods	Do not dump residue into drain. The chemicals must be eliminated in keeping with applicable regulations. Packaging of chemical products must be eliminated in keeping with applicable regulation

SECTION 14 - TRANSPORT INFORMATION

The product is not a hazardous product according to the regulations applicable to transport

SECTION 15 - REGULATORY INFORMATION

15.1 Special regulations/legislation for substance or mixture in terms of safety, health and environment

	Medical device in class IIa according to directive 93/42/EEC
15.2 Chemical safety evaluation	Not available
15.3 U.S. FDA Dental Device	Class II product

SECTION 16 - OTHER INFORMATION

R Phrases

Xn, R22: Harmful if swallowed
 N, R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
 Xi, R36: Irritating to eyes

Hazards Statements H

H302: Harmful if swallowed, acute toxicity category 4
H318: Causes serious eye damage, category 1
H319: Causes serious eye irritation, category 2
H400: Very toxic to aquatic life, Aquatic Acute 1
H41: Very toxic to aquatic life with long lasting effects, Aquatic Chronic 1

Precautionary Statements P

P273: Avoid release to the environment P280: Wear protective gloves/protective clothing/eye protection/face protection P305+351+338: IF IN EYES, rinse cautiously with water for several minutes, remove contact lenses if present and easy to do, continue rinsing.

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