

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

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

Revision date: 18/05/2015

Commercial name:Max Fill Temp jarProduct references:9001614 and 9003790Relevant use of mixture:Temporary filling cement

Details of the supplier of the Safety Data Sheet:

Manufacturer: Authorized EU Representative: Contact:

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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





Signal word Warning Warning

Hazard statements

H302 Harmful if swallowed, cat.4
H 319 Causes serious eye irritation, cat.2
H400 Very 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.

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

eyelids 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

Contact with skin

4.3 Indications of possible immediate medical attention and particular treatment needed

Not available

Not available

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 protectionConsult section 8.6.2 Environmental precautionsDo 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 handling

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

Zinc oxide 8.1 Control parameters

France/Belgium / Spain TLV: 10mg/m³

Germany TLV 4 (inhalable aerosol) mg/m³

Respiratory protection Not necessary in normal use. Wear appropriate gloves. Hand protection 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

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

Not available

products

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects May cause sensitization by eye contact

11.2 Other informations 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 Not available

12.2 Persistence and

degradability

12.3 Bioaccumulation potentialNot available12.4 Mobility in the soilNot available12.5 Results of PBT and vPvBNot available

assessments

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 regulations.

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 available15.3 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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