according to 1907/2006 EC, Article 31

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

1.1. Product identifier

Enamel Plus Temp Powder

Further trade names

Art.-No. TEMP..

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

Use of the substance/mixture

Auxiliary for manufacture of dental prothesis

1.3. Details of the supplier of the safety data sheet

Company name: Micerium S.p.A. Street: Via G. Marconi, 83 Place: I-16036 Avegno (GE), Italy +39-0185-7887870 Telephone: E-mail: quality@micerium.it Contact person: Dr. Eugenio Miceli Internet: www.micerium.com Responsible Department: Dr. Eugenio Miceli

1.4. Emergency telephone Ospedale San Martino Centro Antiveleni (Genoa, Italy) Tel.: +39-010-35-2808

<u>number:</u> (disp. h. 24/24)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

CLP Regulation

Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

CLP Regulation

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Relevant ingredients

CAS No	Chemical name	Quantity		
	EC No	Index No	REACH No	
	Classification (CLP Regulation)			
94-36-0	dibenzoyl peroxide			< 2.5 %
	202-327-6	617-008-00-0		
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1, Aquatic Chronic 1; H241 H319 H317 H410			

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

SECTION 4: First aid measures

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4.1. Description of first aid measures

After inhalation

Provide fresh air. In case of respiratory tract irritation, consult a physician. Rinse mouth.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. If skin irritation occurs: Get medical advice/attention.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth immediately and drink 1 glass of of water.

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.

Water mist

Foam

Carbon dioxide (CO2)

Extinguishing powder

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Avoid dust formation.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment

Take up mechanically.

For cleaning up

Take up mechanically.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Measures to prevent aerosol and dust generation

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

No special measures are necessary.

Further information on storage conditions

Recommended storage temperature 10-25 °C

7.3. Specific end use(s)

No information available.

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	1	5		TWA (8 h)	WEL

8.2. Exposure controls



Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection.

Hand protection

Tested protective gloves must be worn

Butyl caoutchouc (butyl rubber)

NBR (Nitrile rubber)

Permeation time (maximum wear duration): 0,3 mm: 60 min Permeation time (maximum wear duration): 0,11 mm: 10 min

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Dust mask Filter type: P2

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid

Colour:

Melting point/freezing point:

110 °C

Boiling point or initial boiling point and

unbekannt

boiling range:

Flammability: not determined Lower explosion limits: not determined Upper explosion limits: not determined Flash point: unbekannt Auto-ignition temperature: > 400 °C Decomposition temperature: not determined pH-Value: not determined Viscosity / kinematic: not determined Water solubility: No

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:

Vapour pressure:

Density (at 20 °C):

Bulk density (at 20 °C):

Relative vapour density:

Particle characteristics:

not determined

1,16 g/cm³

700-750 kg/m³

not determined

not determined

not applicable

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Solid content: 100 %

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.

Decompostion takes place from temperatures above: > 150 °C

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

May form hazardous decomposition products when exposed to high temperatures. Methyl methacrylate

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SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in CLP Regulation

Acute toxicity

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

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

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

Sensitising effects

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.

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

11.2. Information on other hazards

Other information

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

The product has not been tested.

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

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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Disposal recommendations

Send to a hazardous waste incinerator facility under observation of official regulations.

List of Wastes Code - residues/unused products

WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic 070213

rubber and man-made fibres; waste plastic

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number: No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. 14.2. UN proper shipping name: 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:

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Nο

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to Directive 2012/18/EU (SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile

work protection guideline' (94/33/EC).

Water hazard class (D): 1 - slightly hazardous to water

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

Changes

This data sheet contains changes from the previous version in section(s): 1.

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Abbreviations and acronyms

Org. Perox

Eye Irrit: Eye irritation Skin Sens: Skin sensitisation

Aquatic Chronic: Chronic aquatic hazard CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

EC/EEC: European Community/European Economic Community

EU: European Union

CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate LC50: Lethal concentration, 50%

LD50: Lethal dose, 50% LL50: Lethal loading, 50% EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative

M-factor: Multiplying factor

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Regulations concerning the international carriage of dangerous goods by rail MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container SVHC: Substance of Very High Concern

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Classification for mixtures and used evaluation method according to CLP Regulation

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H241 Heating may cause a fire or explosion.
 H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.

H410 Very toxic to aquatic life with long lasting effects.H412 Harmful to aquatic life with long lasting effects.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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