according to Regulation (EC) No 1907/2006

TempoCem NE_NE-Paste

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

1.1. Product identifier

TempoCem NE NE-Paste

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

Uses advised against

pregnant or breastfeeding people should not work with hazardous substances

1.3. Details of the supplier of the safety data sheet

Company name: DMG Chemisch-Pharmazeutische Fabrik GmbH

Street: Elbgaustraße 248
Place: D-22547 Hamburg

Telephone: +49. (0) 40. 84006-0 Telefax: +49. (0) 40. 84006-222

E-mail: info@dmg-dental.com Internet: www.dmg-dental.com

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Eye Dam. 1; H318 Skin Sens. 1; H317

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

maleic acid

Signal word: Danger

Pictograms:





Hazard statements

H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.

Precautionary statements

P280 Wear protective gloves and eye protection/face protection.

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

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P501 Dispose of contents/container to an appropriate recycling or disposal facility.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

according to Regulation (EC) No 1907/2006

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Relevant ingredients

CAS No	Chemical name			
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No	1272/2008)		
110-16-7	maleic acid			5 - < 10 %
	203-742-5	607-095-00-3	01-2119431592-43	
	Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1, Skin Sens. 1, STOT SE 3; H312 H302 H315 H318 H317 H335			
134-11-2	2-ethoxybenzoic acid			1 - < 5 %
	205-130-3		01-2120227851-58	
	Acute Tox. 4, Eye Irrit. 2; H302 H3			
57-15-8	Chlorbutanol			1 - < 5 %
	200-317-6			
	Acute Tox. 4; H302			

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

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity		
	Specific Conc.	Limits, M-factors and ATE			
110-16-7	203-742-5	maleic acid	5 - < 10 %		
	dermal: LD50	nal: LD50 = 1560 mg/kg; oral: LD50 = 708 mg/kg			
134-11-2	205-130-3	2-ethoxybenzoic acid			
	dermal: LD50 = >2000 mg/kg; oral: LD50 = >300 mg/kg				
57-15-8	200-317-6	Chlorbutanol	1 - < 5 %		
	dermal: LD50	= >2000 mg/kg; oral: LD50 = 510 mg/kg			

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 plenty of water and soap. Medical treatment necessary.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

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.

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Non-flammable.

according to Regulation (EC) No 1907/2006

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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. 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

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

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 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

If handled uncovered, arrangements with local exhaust ventilation have to be used.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink or smoke.

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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls





Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe

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gas/fumes/vapour/spray.

Individual protection measures, such as personal protective equipment

Eye/face protection

Tightly sealed safety glasses.

Hand protection

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

Skin protection

Use of 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: brown
Odour: characteristic

Melting point/freezing point:

Boiling point or initial boiling point and

not determined
not determined

boiling range:

Flammability: not determined Lower explosion limits: not determined Upper explosion limits: not determined Flash point: not applicable Auto-ignition temperature: not determined Decomposition temperature: not determined not determined pH-Value: Water solubility: virtually insoluble

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:

Vapour pressure:

Density:

Relative vapour density:

not determined

not determined

not determined

not determined

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

Evaporation rate: not determined Solid content: not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

according to Regulation (EC) No 1907/2006

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10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

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

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

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

ATEmix calculated

ATE (oral) 5611 mg/kg; ATE (dermal) 31200 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
110-16-7	maleic acid					
	oral	LD50 mg/kg	708	Rat	ECHA	
	dermal	LD50 mg/kg	1560	Rabbit	ECHA	
134-11-2	2-ethoxybenzoic acid					
	oral	LD50 mg/kg	>300	Rat	ECHA	
	dermal	LD50 mg/kg	>2000	Rat	ECHA	
57-15-8	Chlorbutanol					
	oral	LD50 mg/kg	510	Rat	supplier SDS	
	dermal	LD50 mg/kg	>2000	Rat	supplier SDS	

Irritation and corrosivity

Serious eye damage/eye irritation: Causes serious eye damage.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (maleic acid)

Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

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

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

STOT-single exposure

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

according to Regulation (EC) No 1907/2006

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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

Further information

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

SECTION 12: Ecological information

12.1. Toxicity

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

CAS No	Chemical name	Chemical name					
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method
110-16-7	maleic acid						
	Acute fish toxicity	LC50	75 mg/l	l .	Lepomis macrochirus (Bluegill)	ECHA	
	Acute algae toxicity	ErC50 mg/l	74,35		Pseudokirchneriella subcapitata	supplier SDS	OECD 201
	Acute crustacea toxicity	EC50 mg/l	42,81	l .	Daphnia magna (Big water flea)	ECHA	

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name					
	Method	Value	d	Source		
	Evaluation		-			
110-16-7	maleic acid					
	OECD 301B	97,08	28			
Easily biodegradable (concerning to the criteria of the OECD)						
134-11-2	2-ethoxybenzoic acid					
	OECD 301D	70,3%	28			
	Easily biodegradable (concerning to t	he criteria of the OECD)	-			
57-15-8	Chlorbutanol					
	OECD 301E	88%	28			
	Easily biodegradable (concerning to t	he criteria of the OECD)	-			

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
110-16-7	maleic acid	-0,34
134-11-2	2-ethoxybenzoic acid	1,295
57-15-8	Chlorbutanol	2,16

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, annex XIII.

The product has not been tested.

according to Regulation (EC) No 1907/2006

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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

Disposal recommendations

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

Dispose of contents/container to an appropriate recycling or disposal facility.

List of Wastes Code - residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT

KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals

consisting of or containing hazardous substances; hazardous waste

Contaminated packaging

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

SECTION 14: Transport information

l and	trans	nort i	ADR	/PID/
Land	trans	DOLL (AUR	(עוא/

14.1. UN number or ID 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.

Marine transport (IMDG)

14.1. UN number or ID 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.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID 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.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

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

according to Regulation (EC) No 1907/2006

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EU regulatory information

Restrictions on use (REACH, annex XVII):

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): 2 - obviously 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

Abbreviations and acronyms

Acute Tox: Acute toxicity Skin Irrit: Skin irritation Eye Dam: Eye damage Eye Irrit: Eye irritation Skin Sens: Skin sensitisation

STOT SE: Specific target organ toxicity - single exposure

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

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

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).

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

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Eye Dam. 1; H318	Calculation method
Skin Sens. 1; H317	Calculation method

according to Regulation (EC) No 1907/2006

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Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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.)