according to Regulation (EC) No 1907/2006

# Luxatemp MaxProtect\_Catalyst Paste

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

### 1.1. Product identifier

Luxatemp MaxProtect Catalyst 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

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

#### 2.2. Label elements

### Regulation (EC) No 1272/2008

### Special labelling of certain mixtures

EUH208 Contains tert-butylperoxy-3,5,5-trimethylhexanoate (more than 32%). May produce an

allergic reaction.

EUH210 Safety data sheet available on request.

5 - < 10 per cent of the mixture consists of component(s) of unknown acute toxicity

(dermal).

5 - < 10 per cent of the mixture consists of component(s) of unknown acute toxicity

(inhalation).

Contains 40 - < 45 % of components with unknown hazards to the aquatic environment.

### **SECTION 3: Composition/information on ingredients**

## 3.2. Mixtures

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#### Relevant ingredients

CAS No	Chemical name			Quantity		
	EC No	Index No	REACH No			
	Classification (Regulation (EC) No 1272/2008)					
72846-00-5	1-benzyll-5-phenylbarbituric acid			5 - < 10 %		
	276-940-2		01-2120226211-75			
	Acute Tox. 4; H302					
68909-20-6	1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica			1 - < 5 %		
	272-697-1	014-052-00-7				
	STOT RE 2; H373 EUH066					
13122-18-4	tert-butylperoxy-3,5,5-trimethylhexanoate (more than 32%)					
	236-050-7		01-2119498308-25			
	Org. Perox. D, Skin Sens. 1, Aquat	c Acute 1, Aquatic Chronic 1; H242	H317 H400 H410	·		

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				
72846-00-5	276-940-2	1-benzyll-5-phenylbarbituric acid	5 - < 10 %		
	inhalation: Data lacking (gases); dermal: Data lacking; oral: LD50 = 500 mg/kg				
68909-20-6	272-697-1	1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	1 - < 5 %		
	oral: LD50 = >5000 mg/kg				
13122-18-4	236-050-7	tert-butylperoxy-3,5,5-trimethylhexanoate (more than 32%)	< 1 %		
dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg Aquatic Acute 1; H400: M=1					
	Aquatic Chronic	5 1; H410: M=1			

# **SECTION 4: First aid measures**

## 4.1. Description of first aid measures

### After inhalation

Provide fresh air.

### After contact with skin

If skin irritation occurs: Get medical advice/attention.

#### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or 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.

# Unsuitable extinguishing media

Full water jet

# 5.2. Special hazards arising from the substance or mixture

Non-flammable.

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### 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

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

No special measures are necessary.

# Advice on protection against fire and explosion

No special fire protection measures are necessary.

# Advice on general occupational hygiene

Take off contaminated clothing. 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

### Occupational exposure limits

CAS No	Substance	ppm	mg/m³	fib/cm³	Category	Origin
128-37-0	2,6-Ditertiary-butyl-para-cresol	-	2		TWA (8 h)	

# **DNEL/DMEL values**

CAS No	Substance					
DNEL type		Exposure route	Effect	Value		
128-37-0	2,6-Di-tert-butyl-4-methylphenol					
Worker DNEL,	long-term	inhalation	systemic	3,5 mg/m³		
Worker DNEL, long-term		dermal	systemic	0,5 mg/kg bw/day		

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#### **PNEC values**

CAS No	Substance		
Environmental compartment Value			
128-37-0 2,6-Di-tert-butyl-4-methylphenol			
Freshwater 0,000199 mg/l			
Freshwater (intermittent releases)		0,00199 mg/l	
Marine water		0,000199 mg/l	
Freshwater sediment		0,0996 mg/kg	
Marine sediment		0,00996 mg/kg	
Soil		0,04769 mg/kg	

# 8.2. Exposure controls



#### Individual protection measures, such as personal protective equipment

#### Eve/face protection

Wear eye protection/face protection.

#### 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:

Odour: characteristic

Melting point/freezing point:

Boiling point or initial boiling point and

not determined
not determined

boiling range:

not determined Flammability: Lower explosion limits: not determined Upper explosion limits: not determined Flash point: not applicable Auto-ignition temperature: not determined not determined Decomposition temperature: pH-Value: not determined Water solubility: The study does not need to be conducted

he study does not need to be conducted because the substance is known to be insoluble in water.

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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
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.

#### 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) 6120 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

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CAS No	Chemical name							
	Exposure route	Dose	Species	Source	Method			
72846-00-5	1-benzyll-5-phenylbarbituric acid							
	oral	LD50 500 mg/kg	Rat	ECHA	OECD 423			
	dermal	Data lacking						
	inhalation	Data lacking						
68909-20-6	1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica							
	oral	LD50 >5000 mg/kg	Rat	supplier SDS	OECD 401			
13122-18-4	tert-butylperoxy-3,5,5-trim	ethylhexanoate (more th	an 32%)					
	oral	LD50 >5000 mg/kg	Rat	supplier SDS				
	dermal	LD50 >2000 mg/kg	Rat	supplier SDS				

#### Irritation and corrosivity

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

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

#### Sensitising effects

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

Contains tert-butylperoxy-3,5,5-trimethylhexanoate (more than 32%). May produce an allergic reaction.

# 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.

# 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 not 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.

according to Regulation (EC) No 1907/2006

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CAS No	Chemical name						
	Aquatic toxicity	Dose		[h]   [d]	Species	Source	Method
72846-00-5	1-benzyll-5-phenylbarbituric acid						
	Acute crustacea toxicity	EC50	>50 mg/l		Daphnia magna (Big water flea)	ECHA	OECD 202
68909-20-6	1,1,1-trimethyl-N-(trimeth	ıylsilyl)-, hyd	rolysis produ	cts with s	silica		
	Acute fish toxicity	LC50 mg/l	>1000	96 h	Danio rerio (zebrafish)	supplier SDS	
	Acute algae toxicity	ErC50 mg/l	>10000	72 h	Scenedesmus subspicatus	supplier SDS	
	Acute crustacea toxicity	EC50 mg/l	>100		Daphnia magna (Big water flea)	supplier SDS	
13122-18-4	tert-butylperoxy-3,5,5-trir	nethylhexan	oate (more th	an 32%)			
	Acute fish toxicity	LC50	7 mg/l		Oncorhynchus mykiss (Rainbow trout)	supplier SDS	
	Acute algae toxicity	ErC50 mg/l	0,51	72 h	Pseudokirchneriella subcapitata	ECHA	
	Acute crustacea toxicity	EC50 mg/l	>100	48 h	Daphnia magna (Big water flea)	supplier SDS	

#### 12.2. Persistence and degradability

The product has not been tested

е р.	' <u>-</u>							
CAS No	Chemical name							
	Method	Value	d	Source				
	Evaluation		-	•				
13122-18-4	tert-butylperoxy-3,5,5-trimethylhexanoate (more than 32%)							
	OECD 301D	72%	28					
	Easily biodegradable (concerning to the 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
72846-00-5	1-benzyll-5-phenylbarbituric acid	2,57
13122-18-4	tert-butylperoxy-3,5,5-trimethylhexanoate (more than 32%)	5,16

### 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.

# 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**

Avoid release to the environment.

## **SECTION 13: Disposal considerations**

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### 13.1. Waste treatment methods

### **Disposal recommendations**

Do not allow to enter into surface water or drains. 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

Wash with plenty of water. Completely emptied packages can be recycled.

### **SECTION 14: Transport information**

### Land transport (ADR/RID)

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.

#### 14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

#### 14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

### **SECTION 15: Regulatory information**

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

### **EU** regulatory information

Information according to Directive

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

2012/18/EU (SEVESO III):

National regulatory information

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**

according to Regulation (EC) No 1907/2006

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#### Abbreviations and acronyms

Org. Perox

Acute Tox: Acute toxicity
Skin Sens: Skin sensitisation

STOT RE: Specific target organ toxicity - repeated exposure

Aquatic Acute: Acute aquatic hazard
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** 

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

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).

### Relevant H and EUH statements (number and full text)

H242 Heating may cause a fire.
H302 Harmful if swallowed

H317 May cause an allergic skin reaction.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.
EUH066 Repeated exposure may cause skin dryness or cracking.

EUH208 Contains tert-butylperoxy-3,5,5-trimethylhexanoate (more than 32%). May produce an

allergic reaction.

EUH210 Safety data sheet available on request.

#### **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.)