

according to Regulation (EC) No 1907/2006

Gingivamoll® paint colours

Revision date: 28.08.2018

Product code: 10366

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Gingivamoll® paint colours

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

Epithesis material for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)

1.4. Emergency telephone number:

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Hazard Statements:

Causes skin irritation.

2.2. Label elements**Regulation (EC) No. 1272/2008**

Signal word: Warning

Pictograms:

**Hazard statements**

H315 Causes skin irritation.

Precautionary statements

P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

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3.2. Mixtures

Chemical characterization

Containes polydimethylsiloxanes and pigments.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
1330-20-7	xylene			10 - < 15 %
	215-535-7	601-022-00-9		
	Flam. Liq. 3, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2; H226 H332 H312 H315			
541-02-6	Decamethylcyclotetrasiloxane			1 - < 5 %
	208-764-9		01-2119511367-43	
100-41-4	ethylbenzene			1 - < 5 %
	202-849-4	601-023-00-4		
	Flam. Liq. 2, Acute Tox. 4, STOT RE 2, Asp. Tox. 1; H225 H332 H373 H304			
67-63-0	"propan-2-ol; isopropyl alcohol; isopropanol"			1 - < 5 %
	200-661-7	603-117-00-0		
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336			
556-67-2	octamethylcyclotetrasiloxane			< 1,5 %
	209-136-7	014-018-00-1	01-2119529238-36	
	Flam. Liq. 3, Repr. 2, Aquatic Chronic 4; H226 H361f H413			
108-88-3	toluene			< 1 %
	203-625-9	601-021-00-3		
	Flam. Liq. 2, Repr. 2, Skin Irrit. 2, STOT SE 3, STOT RE 2, Asp. Tox. 1; H225 H361d H315 H336 H373 H304			

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

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

 Rinse mouth immediately and drink plenty of water.
Do not induce vomiting. If you feel unwell, seek medical advice.

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.

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SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

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**

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

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). 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.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed.

Advice on storage compatibility

No special measures are necessary.

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

7.3. Specific end use(s)

Silicone material for the fabrication of gingival epithesis.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

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Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
100-41-4	Ethylbenzene	100	441		TWA (8 h)	WEL
		125	552		STEL (15 min)	WEL
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
		500	1250		STEL (15 min)	WEL
108-88-3	Toluene	50	191		TWA (8 h)	WEL
		100	384		STEL (15 min)	WEL
1330-20-7	Xylene: mixed isomers	50	220		TWA (8 h)	WEL
		100	441		STEL (15 min)	WEL

Biological Monitoring Guidance Values (EH40)

CAS No	Substance	Parameter	Value	Test material	Sampling time
1330-20-7	Xylene, o-, m-, p- or mixed isomers	methyl hippuric acid (creatinine)	650 mmol/mol	urine	Post shift

8.2. Exposure controls

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.
Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Wear eye/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.

Suitable are gloves of the following material: NBR (Nitrile rubber)

Skin protection

Wear suitable 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: red , blue
Odour: odourless

Test method

pH-Value: not determined

Changes in the physical state

Melting point: not determined
Initial boiling point and boiling range: not determined

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Flash point: >100 °C DIN 51755

Flammability

Solid: not applicable

Gas: not applicable

Lower explosion limits: not determined

Upper explosion limits: not determined

Ignition temperature: >200 °C DIN 51794

Auto-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: >250 °C

Oxidizing properties

Not oxidizing.

Vapour pressure: not determined

Density: not determined

Water solubility: insoluble

Solubility in other solvents

not determined

Partition coefficient: not determined

Vapour density: not determined

Evaporation rate: not determined

9.2. Other information

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

Temperatures > 150°C/ 302 °F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

At a temperature of approx. 150°C/ 302°F a small amount of formaldehyde can be released by oxidative degradation.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
1330-20-7	xylene				
	oral	LD50 mg/kg 4300	Rat	GESTIS	
	dermal	LD50 mg/kg >1700	Rabbit	GESTIS	
	inhalation (4 h) vapour	LC50 21,7 mg/l	Rat	GESTIS	
	inhalation aerosol	ATE 1,5 mg/l			
541-02-6	Decamethylcyclotetrasiloxane				
	oral	LD50 mg/kg >24100	Rat	GESTIS	
	dermal	LD50 mg/kg >2000	Rabbit		OECD 402
	inhalation (4 h) vapour	LC50 8,67 mg/l	Rat		OECD 403
100-41-4	ethylbenzene				
	oral	LD50 mg/kg 3500	Rat	GESTIS	
	dermal	LD50 mg/kg 15400	Rabbit	GESTIS	
	inhalation (4 h) vapour	LC50 17,2 mg/l	Rat		
	inhalation aerosol	ATE 1,5 mg/l			
67-63-0	"propan-2-ol; isopropyl alcohol; isopropanol"				
	oral	LD50 mg/kg 5050	Rat	GESTIS	
	dermal	LD50 mg/kg 12800	Rabbit	GESTIS	
556-67-2	octamethylcyclotetrasiloxane				
	oral	LD50 mg/kg 4800	Rat		OECD 401
	dermal	LD50 mg/kg >2400	Rabbit		OECD 402
	inhalation (4 h) vapour	LC50 36 mg/l	Rat	GESTIS	OECD 403
108-88-3	toluene				
	oral	LD50 mg/kg 636	Ratte	GESTIS	
	dermal	LD50 mg/kg 12200	Kaninchen	GESTIS	
	inhalation (4 h) vapour	LC50 49 mg/l	Ratte	GESTIS	

Irritation and corrosivity

Causes skin irritation.

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.

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.

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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.

Additional information on tests

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

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
1330-20-7	xylene					
	Acute fish toxicity	LC50 mg/l	15,7	96 h		GESTIS
	Acute crustacea toxicity	EC50	8,5 mg/l	48 h		GESTIS
100-41-4	ethylbenzene					
	Acute fish toxicity	LC50 mg/l	80,0	96 h		GESTIS
	Acute algae toxicity	ErC50	3,6 mg/l	96 h		GESTIS
	Acute crustacea toxicity	EC50 mg/l	16,2	48 h		GESTIS
67-63-0	"propan-2-ol; isopropyl alcohol; isopropanol"					
	Acute fish toxicity	LC50 mg/l	9640	96 h		GESTIS
	Acute algae toxicity	ErC50 mg/l	>100	72 h	Scenedesmus subspicatus	
	Acute crustacea toxicity	EC50 mg/l	>100	48 h	Daphnia magna (Big water flea)	
108-88-3	toluene					
	Acute fish toxicity	LC50	13 mg/l	96 h	Carassius	IUCLID
	Acute algae toxicity	ErC50 mg/l	12,5	72 h		GESTIS
	Acute crustacea toxicity	EC50 mg/l	9,24	48 h		GESTIS

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
67-63-0	"propan-2-ol; isopropyl alcohol; isopropanol"			
	Activated sludge	53%	5	
	Readily biodegradable (according to OECD criteria).			
556-67-2	octamethylcyclotetrasiloxane			
		3,7%	29	
	Not readily biodegradable (according to OECD criteria)			

12.3. Bioaccumulative potential

The product has not been tested.

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Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
100-41-4	ethylbenzene	3,15
67-63-0	"propan-2-ol; isopropyl alcohol; isopropanol"	<=4

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Decamethylcyclotetrasiloxane (D5) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D5 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D5 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D5 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

Octamethylcyclotetrasiloxane (D4) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for PBT and vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D4 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D4 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D4 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

12.6. 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

Advice on disposal

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.

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:

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.

Inland waterways transport (ADN)

14.1. UN 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.

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Marine transport (IMDG)

- 14.1. UN 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:** 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. Transport in bulk according to Annex II of Marpol and the IBC Code

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

Restrictions on use (REACH, annex XVII):

Entry 48: toluene

Additional information

The mixture contains substances of very high concern (SVHC candidates):

Decamethylcyclopentasiloxane (D5), CAS no. 541-02-6

Octamethylcyclotetrasiloxane (D4), CAS no. 556-67-2

National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

Water contaminating class (D): 3 - highly water contaminating

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

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

Classification	Classification procedure
Skin Irrit. 2; H315	Calculation method

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Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H336	May cause drowsiness or dizziness.
H361d	Suspected of damaging the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.

Further Information

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

Identified uses

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
1	Gewerblich	-	-	-	-	-	-	-	2

LCS: Life cycle stages

PC: Product categories

ERC: Environmental release categories

TF: Technical functions

SU: Sectors of use

PROC: Process categories

AC: Article categories

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