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

1.1. Product identifier

Gingivamoll® protective laquer

UFI: J47W-707G-000K-DKFU

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:
Flammable liquid: Flam. Liq. 2
Skin corrosion/irritation: Skin Irrit. 2
Serious eye damage/eye irritation: Eye Irrit. 2
Specific target organ toxicity - single exposure: STOT SE 3
Specific target organ toxicity - repeated exposure: STOT RE 2
Hazardous to the aquatic environment: Aquatic Chronic 2
Hazard Statements:
Highly flammable liquid and vapour.
Causes skin irritation.
Causes serious eye irritation.
May cause drowsiness or dizziness.
May cause damage to organs through prolonged or repeated exposure.
Toxic to aquatic life with long lasting effects.

2.2. Label elements

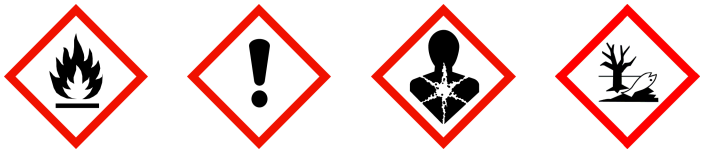
Regulation (EC) No. 1272/2008

Hazard components for labelling

methylcyclohexane
xylene

Signal word: Danger

Pictograms:



Hazard statements

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H373	May cause damage to organs through prolonged or repeated exposure.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P273	Avoid release to the environment.
P370+P378	In case of fire: Use Carbon dioxide (CO2), Foam,Extinguishing powder to extinguish.
P391	Collect spillage.
P403+P235	Store in a well-ventilated place. Keep cool.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
108-87-2	methylcyclohexane			70 - < 75 %
	203-624-3	601-018-00-7		
	Flam. Liq. 2, Skin Irrit. 2, STOT SE 3, Asp. Tox. 1, Aquatic Chronic 2; H225 H315 H336 H304 H411			
1330-20-7	xylene			10 - < 15 %
	215-535-7	601-022-00-9	01-2119488216-32	
	Flam. Liq. 3, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, STOT RE 2, Asp. Tox. 1, Aquatic Chronic 3; H226 H332 H312 H315 H319 H335 H373 H304 H412			

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. Medical treatment necessary.

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. Medical treatment necessary.

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. Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

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

Carbon dioxide (CO2), Foam, Extinguishing powder.

Unsuitable extinguishing media

Water.

5.2. Special hazards arising from the substance or mixture

Highly flammable. Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Use water spray jet to protect personnel and to cool endangered containers. 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

Remove all sources of ignition. 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 uncontrolled discharge of product into the environment. Danger of explosion

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

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

Keep away from sources of ignition. - No smoking. Take precautionary measures against static discharges. Vapours can form explosive mixtures with air.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations. Keep in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints on joint storage

Do not store together with: Oxidising agent . Pyrophoric or self-heating substances.

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)

Liquid for coating of silicone based epithesis.
For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
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

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

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

Suitable eye protection: goggles.

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: FKM (fluoro rubber)

Skin protection

Flame-retardant protective clothing. Wear anti-static footwear and 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:	liquid:
Colour:	colourless
Odour:	like benzene

Test method

pH-Value:	not determined	
Changes in the physical state		
Melting point:	not determined	
Initial boiling point and boiling range:	>99 °C	DIN 51356
Flash point:	-4 °C	DIN 51755
Flammability		
Solid:	not applicable	
Gas:	not applicable	
Lower explosion limits:	1,1 vol. %	
Upper explosion limits:	6,7 vol. %	
Ignition temperature:	not determined	
Auto-ignition temperature		
Solid:	not applicable	
Gas:	not applicable	
Decomposition temperature:	not determined	
Oxidizing properties		
Not oxidizing.		
Vapour pressure: (at 20 °C)	48 hPa	
Density (at 20 °C):	0,76 g/cm³	DIN 51757
Water solubility:	insoluble	
Solubility in other solvents		
not determined		
Partition coefficient:	not determined	
Viscosity / dynamic: (at 23 °C)	15-20 mPa·s	BROOKFIELD
Vapour density:	not determined	
Evaporation rate:	not determined	

9.2. Other information

Solid content:	not determined	

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with : strong oxidising agents. The product may attack same plastic materials.

10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Vapours can form explosive mixtures with air. Higher temperatures advance the formulation of explosive vapour-air mixtures, therefore don't expose the product to increased temperatures.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

The following applies for the silicone content of the product: At temperature of appr. 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.

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
108-87-2	methylcyclohexane					
	oral	LD50 mg/kg	> 3200	Rat	GESTIS	
	dermal	LD50 mg/kg	86000	Rabbit		
1330-20-7	xylene					
	oral	LD50 mg/kg	3500	Rat	GESTIS	
	dermal	LD50 mg/kg	>1700	Rabbit	GESTIS	
	inhalation (4 h) vapour	LC50 mg/l	29,08	Rat	GESTIS	
	inhalation aerosol	ATE	1,5 mg/l			

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

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

May cause drowsiness or dizziness. (methylcyclohexane)

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure. (xylene)

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

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] | [d]	Species	Source	Method
108-87-2	methylcyclohexane					
	Acute fish toxicity	LC50 58,5 mg/l	96 h		GESTIS	
	Acute crustacea toxicity	EC50 1,47 mg/l	48 h	Daphnia magna	ECOTOX	
1330-20-7	xylene					
	Acute fish toxicity	LC50 2,661-4,093 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)		
	Acute crustacea toxicity	EC50 3,82 mg/l	48 h			

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
108-87-2	methylcyclohexane	3,88
1330-20-7	xylene	3,15

BCF

CAS No	Chemical name	BCF	Species	Source
1330-20-7	xylene	0,6-15		

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identivied as PBT/ vPvB substances

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

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.

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number: UN 1866

14.2. UN proper shipping name: Resin solution

14.3. Transport hazard class(es): 3

14.4. Packing group:	II
Hazard label:	3
Classification code:	F1
Limited quantity:	5 L/ 30 kg
Hazard No:	33
Tunnel restriction code:	D/E

Other applicable information (land transport)

Flammable licquid

Marine transport (IMDG)

14.1. UN number:	UN 1866
14.2. UN proper shipping name:	Resin solution
14.3. Transport hazard class(es):	3
14.4. Packing group:	III
Hazard label:	3
Marine pollutant:	P
Limited quantity:	5 L/ 30 kg
EmS:	F-E, S-E

Other applicable information (marine transport)

Flash point: -4°C c.c.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	UN 1866
14.2. UN proper shipping name:	Resin solution
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Limited quantity Passenger:	1 L/ 30 kg
Passenger LQ:	Y341
Excepted quantity:	E2
IATA-packing instructions - Passenger:	353
IATA-max. quantity - Passenger:	5 L
IATA-packing instructions - Cargo:	364
IATA-max. quantity - Cargo:	60 L

Other applicable information (air transport)

Flammable licquid

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: yes

14.6. Special precautions for user

Warning: Combustible liquid.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

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

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

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
Flam. Liq. 2; H225	On basis of test data
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method
STOT SE 3; H336	Calculation method
STOT RE 2; H373	Calculation method
Aquatic Chronic 2; H411	Calculation method

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H373	May cause damage to organs through prolonged or repeated exposure.
H411	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.

Identified uses

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

LCS: Life cycle stages
SU: Sectors of use
PC: Product categories
PROC: Process categories
ERC: Environmental release categories
AC: Article categories
TF: Technical functions

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