

according to Regulation (EC) No 1907/2006

**dip coat**

Revision date: 17.12.2020

Product code: 620

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

dip coat

UFI: 0E9Y-A06T-E008-U8X5

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

Silicone based lacquer for use in audiology.

**1.3. Details of the supplier of the safety data sheet****Manufacturer**

Company name: DETAX GmbH & Co. KG  
Street: Carl-Zeiss-Strasse  
Place: D-76275 Ettlingen  
Telephone: +49 7243/510-0  
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.)

Telefax: +49 7243/510-100

**Importer / Distributer**

Company name: Ivoclar Vivadent Ltd  
Place: PO Box 303011, North Harbour, Auckland, 0751  
Telephone: +64 9 914 9999  
e-mail: info@ivoclarvivadent.com  
Telefax: Fax: +64 9 914 9990

**1.1. Emergency telephone number:**

0800 764 766  
Poisons Hotline (24 hours / 7 days) NZ: National Poison Centre (New Zealand)

**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 Dam. 1

Specific target organ toxicity - single exposure: STOT SE 3

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 damage.

May cause respiratory 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**

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#### Hazard components for labelling

methylcyclohexane  
xylene  
triacetoxymethylsilane

**Signal word:** Danger

#### Pictograms:



#### Hazard statements

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H318	Causes serious eye damage.
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.

#### Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
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.
P370+P378	In case of fire: Use Carbon dioxide (CO <sub>2</sub> ), Foam, Extinguishing powder to extinguish.
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

##### Chemical characterization

Polydimethylsiloxane with functional groups in organic solvents.

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#### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
108-87-2	methylcyclohexane			45 - < 50 %
	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			20 - < 25 %
	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			
4253-34-3	triacetoxymethylsilane			1 - < 5 %
	224-221-9		01-2119962266-32	
	Acute Tox. 4, Skin Corr. 1C, Eye Dam. 1; H302 H314 H318 EUH014			

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 plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. 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.

###### 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 unimpeded 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 (CO<sub>2</sub>), 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.

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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. Explosion risk in case of fire.

#### 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 exhaust 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: . Pyrophoric or self-heating substances. Oxidising agent

#### 7.3. Specific end use(s)

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

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
1330-20-7	Xylene: mixed isomers	50	220		TWA (8 h)	WEL
		100	441		STEL (15 min)	WEL

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#### 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, drink, smoke, sniff.

##### 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: transparent  
 Odour: Xylene/ Acetic acid

##### 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: <1 °C DIN 51755  
 Sustaining combustion: Not sustaining combustion

##### Flammability

Solid: not applicable  
 Gas: not applicable

##### Explosive properties

The product is not: Explosive.

Lower explosion limits: 1,1 vol. %  
 Upper explosion limits: 6,7 vol. %

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#### Auto-ignition temperature

Solid: not applicable  
Gas: not applicable

Decomposition temperature: not determined

#### Oxidizing properties

Not oxidizing.

Vapour pressure: 48 hPa  
(at 20 °C)

Density (at 20 °C): 0,90 g/cm<sup>3</sup> DIN 51757

Water solubility: insoluble

#### Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic: 120 mPa·s CP  
(at 23 °C)

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 some 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.

#### 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.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
108-87-2	methylcyclohexane				
	oral	LD50 > 3200 mg/kg	Rat	GESTIS	
	dermal	LD50 86000 mg/kg	Rabbit		
1330-20-7	xylene				
	oral	LD50 3500 mg/kg	Rat	GESTIS	
	dermal	LD50 >1700 mg/kg	Rabbit	GESTIS	
	inhalation (4 h) vapour	LC50 29,08 mg/l	Rat	GESTIS	
	inhalation aerosol	ATE 1,5 mg/l			
4253-34-3	triacetoxymethylsilane				
	oral	LD50 1600 mg/kg	Rat	OECD 401	

#### Irritation and corrosivity

Causes skin irritation.

Causes serious eye damage.

#### 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 respiratory irritation. (xylene)

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 life with long lasting effects.

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

@1301.B130039 Handle contaminated packages in the same way as the substance itself.

### SECTION 14: Transport information

#### Land transport (ADR/RID)

<b>14.1. UN number:</b>	UN 1866
<b>14.2. UN proper shipping name:</b>	Resin solution
<b>14.3. Transport hazard class(es):</b>	3
<b>14.4. Packing group:</b>	II



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

#### 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:** II  
 Hazard label: 3  
 Marine pollutant: yes  
 Special Provisions: -  
 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  
 IATA-packing instructions - Passenger: 353  
 IATA-max. quantity - Passenger: 5 L  
 IATA-packing instructions - Cargo: 364  
 IATA-max. quantity - Cargo: 60 L

#### 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

Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.  
 Standard for the Uniform Scheduling of Medicines and Poisons.  
 Carcinogen classification under WHS Regulation 2011, Schedule 10.  
 Notification status in accordance with section 3 and current national legislation.  
 HSNO Approval: HSR001198, HSR007211, HSR007291  
 EPA NZ Classes of hazardous properties:

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Classification 3.1B Flammable Liquids: high hazard

Classification 6.1E (All) Acutely toxic

Classification 6.3B Mildly irritating to the skin

Classification 6.4A Irritating to the eye

Classification 9.1D (All) Slightly harmful in the aquatic environment or are otherwise designed for biocidal action

Classification 3.1C Flammable liquid - very high hazard

Classification 6.1D (All) Substances that are acutely toxic - Harmful

Classification 6.1D (O)

Classification 6.1D (D)

Classification 6.1E (I) Substances that are acutely toxic – May be harmful, aspiration hazard

Classification 6.3B Substances that are mildly irritating to the skin

Classification 6.4A Substances that are irritating to the eye

Classification 6.8B Substances that are suspected human reproductive or developmental toxicants

Classification 6.9B (All) Substances that are harmful to human target organs or systems

Classification 6.9B (O)

Classification 9.1D (All) Substances that are slightly harmful to the aquatic environment or are otherwise designed for biocidal action

Classification 9.1D (F)

Classification 9.1D (C)

Classification 9.1D (A)

Classification 9.3C Substances that are harmful to terrestrial vertebrates

Classification 6.1D (All) Acutely toxic

Classification 8.2C Corrosive to dermal tissue

Classification 8.3A Corrosive to ocular tissue

Classification 9.3B Ecotoxic to terrestrial vertebrates

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#### 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%  
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  
DNEL: Derived No Effect Level  
DMEL: Derived Minimal Effect Level  
PNEC: Predicted No Effect Concentration  
ATE: Acute toxicity estimate  
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  
RID: Regulations concerning the international carriage of dangerous goods by rail  
EmS: Emergency Schedules  
MFAG: Medical First Aid Guide  
ICAO: International Civil Aviation Organization  
MARPOL: International Convention for the Prevention of Marine Pollution from Ships  
IBC: Intermediate Bulk Container  
VOC: Volatile Organic Compounds  
SVHC: Substance of Very High Concern  
@1602.B016012

#### 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 Dam. 1; H318	Calculation method
STOT SE 3; H335	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.

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H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
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.
EUH014	Reacts violently with water.

#### 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.

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