

according to Regulation (EC) No 1907/2006

ImplanTITAN Removable Implant Cement 4:1

Revision date: 01.08.2019

Product code: HAS-0001

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier****ImplanTITAN Removable Implant Cement 4:1** HAS-0001**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/mixture**

Provisional cement for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Company name: Hexa Dental

Street: 5211 E. Washington Blvd, Suite #2-201

Place: Commerce, CA

Telephone: 626-677-0486

e-mail: info@hexadental.com

Internet: www.hexadental.com

Responsible Department: Regulatory Affairs

1.4. Emergency telephone**number:** (800) 255-3924 USA (813)248-0585 International (Chemtel 24 hrs)**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Respiratory or skin sensitisation: Skin Sens. 1B

Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements:

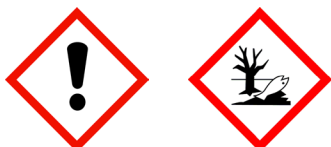
May cause an allergic skin reaction.

Toxic to aquatic life with long lasting effects.

2.2. Label elements**Regulation (EC) No. 1272/2008****Hazard components for labelling**

aliphatic urethane acrylate

2-hydroxyethyl methacrylate

Signal word: Warning**Pictograms:****Hazard statements**

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

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P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.
P501	Dispose of contents/ container in accordance with local and national regulations.

Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

Mixture of methacrylic resins with auxiliary matters.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
	aliphatic urethane acrylate			10 - < 15 %
	906-949-5		01-2120266262-	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
72846-00-5	1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione			5 - < 10 %
			01-2120226211-75	
	Acute Tox. 4; H302			
6606-59-3	1,6-hexanediol dimethacrylate			5 - < 10 %
	229-551-7			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
868-77-9	2-hydroxyethyl methacrylate			< 1 %
	212-782-2	607-124-00-X		
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			
3380-34-5	triclosan; 2,4,4'-trichloro-2'-hydroxy-diphenyl-ether; 5-chloro-2-(2,4-dichlorophenoxy)phenol			< 1 %
	222-182-2	604-070-00-9		
	Skin Irrit. 2, Eye Irrit. 2, Aquatic Acute 1 (M-Factor = 100), Aquatic Chronic 1 (M-Factor = 100); H315 H319 H400 H410			
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate			< 1 %
	244-289-3		01-2120766649-35	
	Repr. 1B; H360			

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. When in doubt or if symptoms are observed, get medical advice.

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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

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation 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 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**

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.

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

Keep container tightly closed.

Hints on joint storage

Keep away from spontaneous flammable or combustible substances.

Further information on storage conditions

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

7.3. Specific end use(s)

Luting cement for implant retained dental restorations.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****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, drink, smoke, sniff.

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: Butyl caoutchouc (butyl 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, low-viscosity
Colour:	base: white, catalyst: transparent
Odour:	aromatic

Test method

pH-Value:	not determined
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Changes in the physical state

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

Flash point:	>100 °C	DIN 51755
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Sustaining combustion:	Not sustaining combustion
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Flammability

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Solid: not applicable

Gas: not applicable

Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined

Upper explosion limits: not determined

Auto-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

Not oxidizing.

Vapour pressure:
(at 20 °C) <1 hPaDensity (at 20 °C): 1,1 g/cm³ DIN 51757

Water solubility: insoluble

Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic:
(at 23 °C) 40000 mPa·s Rheostress

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 reactionsReacts with :
oxidising agents, radicals forming substances or heavy metal ions.**10.4. Conditions to avoid**

Ultra-violet light and daylight initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of light. Keep at temperature not exceeding 25°C/ 77°F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

In case of fire, acrid acrylic fumes may occur.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

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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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
72846-00-5	1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione				
	oral	ATE 500 mg/kg			
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 5050 mg/kg	Rat		
	dermal	LD50 >3000 mg/kg	Rabbit		
3380-34-5	triclosan; 2,4,4'-trichloro-2'-hydroxy-diphenyl-ether; 5-chloro-2-(2,4-dichlorophenoxy)phenol				
	oral	LD50 >5000 mg/kg	Rat	OECD 401	
	dermal	LD50 >6000 mg/kg	Rat	OECD 402	
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate				
	oral	LD50 14,900 mg/kg	Rat		

Irritation and corrosivity

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

Sensitising effects

May cause an allergic skin reaction. (aliphatic urethane acrylate; 2-hydroxyethyl methacrylate)

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.

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**

Toxic to aquatic life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50 227 mg/l	96 h	Pimephales promelas		
3380-34-5	triclosan; 2,4,4'-trichloro-2'-hydroxy-diphenyl-ether; 5-chloro-2-(2,4-dichlorophenoxy)phenol					
	Acute fish toxicity	LC50 0,54 mg/l	96 h	Brachydanio rerio (zebra-fish)	OECD 203	
	Acute algae toxicity	ErC50 0,00161 mg/l	72 h	Desmodesmus subspicatus.		
	Acute crustacea toxicity	EC50 0,427 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
	Fish toxicity	NOEC 0,0341 mg/l	96 d	Oncorhynchus mykiss (Rainbow trout)	OPP 72-4	
	Crustacea toxicity	NOEC 0,04 mg/l	21 d	Daphnia magna (Big water flea)	OECD 211	
	Acute bacteria toxicity	(11 mg/l)	3 h	Activated sludge	OECD 209	
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate					
	Acute fish toxicity	LC50 0,235 mg/l	96 h	QSAR		
	Acute algae toxicity	ErC50 <0,015 mg/l	72 h	Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50 >0,031 mg/l	48 h	Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(1000 mg/l)	3 h	Activated sludge		

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
868-77-9	2-hydroxyethyl methacrylate			
	84	%	28	
	Leicht biologisch abbaubar			
3380-34-5	triclosan; 2,4,4'-trichloro-2'-hydroxy-diphenyl-ether; 5-chloro-2-(2,4-dichlorophenoxy)phenol			
	BOD (% of ThOD).	37%	28	OECD 301B/ ISO 9439/ EEC 92/69/V, C.4-C
	Not readily biodegradable (according to OECD criteria)			
	specific analysis.	99,4%	14	OECD 302B/ ISO 9888/ EEC 92/69/V, C.9

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-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione	2,3
868-77-9	2-hydroxyethyl methacrylate	0,47

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BCF

CAS No	Chemical name	BCF	Species	Source
3380-34-5	triclosan; 2,4,4'-trichloro-2'-hydroxy-diphenyl-ether; 5-chloro-2-(2,4-dichlorophenoxy)phenol	4.157	Brachydanio rerio (zebra-fish)	OECD 305

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****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:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains: Triclosan
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Classification code:	M6
Limited quantity:	5 L / 30 kg
Hazard No:	90
Tunnel restriction code:	E

Other applicable information (land transport)

Contains: Triclosan

Marine transport (IMDG)

14.1. UN number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains Triclosan
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Marine pollutant:	P
Limited quantity:	5 L / 30 kg

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EmS: F-A, S-F

Other applicable information (marine transport)

Contains Triclosan

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: UN 3082
14.2. UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Contains Triclosan
14.3. Transport hazard class(es): 9
14.4. Packing group: III
Hazard label: 9
Limited quantity Passenger: 30 kg G
Passenger LQ: Y964
IATA-packing instructions - Passenger: 964
IATA-max. quantity - Passenger: 450 L
IATA-packing instructions - Cargo: 964
IATA-max. quantity - Cargo: 450 L

Other applicable information (air transport)

Contains Triclosan

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: yes

14.6. Special precautions for user

No information available.

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****EU regulatory information**

Information according to 2012/18/EU (SEVESO III): E2 Hazardous to the Aquatic Environment

Additional information

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

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
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**

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

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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
Skin Sens. 1B; H317	Calculation method
Aquatic Chronic 2; H411	Calculation method

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360	May damage fertility or the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

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.

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