

according to Regulation (EC) No 1907/2006

Etchant Gel - Etchant Gel S

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

1.1. Product identifier

Etchant Gel - Etchant Gel S

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

Use of the substance/mixture

for dental use only

1.3. Details of the supplier of the safety data sheet

Company name: COLTENE/Whaledent AG Street: Feldwiesenstrasse 20 Place: CH-9450 Altstätten +41 (71) 75 75 300 Telephone: Telefax: +41 (71) 75 75 301 e-mail: info.ch@coltene.com Internet: www.coltene.com Responsible Department: Regulatory Affairs msds@coltene.com

1.4. Emergency telephone +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Skin corrosion/irritation: Skin Corr. 1B

Serious eye damage/eye irritation: Eye Dam. 1

Hazard Statements:

Causes severe skin burns and eye damage.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Phosphoric acid

Signal word: Danger

Pictograms:



Hazard statements

H314 Causes severe skin burns and eye damage.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face 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.

P337+P313 If eye irritation persists: Get medical advice/attention.

P302+P352 IF ON SKIN: Wash with plenty of water.

P332+P313 If skin irritation occurs: Get medical advice/attention.

Additional advice on labelling

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact



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with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity	
	EC No	Index No	REACH No		
	Classification according to R	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
7664-38-2	Phosphoric acid	Phosphoric acid			
	231-633-2	015-011-00-6			
	Skin Corr. 1B; H314	*			

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated clothing immediatley and dispose off safely.

After inhalation

Provide fresh air. In case of respiratory tract irritation, consult a physician.

After contact with skin

After contact with skin, wash immediately with: Water and soap.

After contact with eyes

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

After ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Medical treatment necessary.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.

Additional information

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.

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). Clear contaminated areas thoroughly.

SECTION 7: Handling and storage

7.1. Precautions for safe handling



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Advice on safe handling

Avoid contact with skin and eyes.

for professional use only Keep out of the reach of children.

Observe instructions for use.

7.2. Conditions for safe storage, including any incompatibilities

Further information on storage conditions

Recommended storage temperature: 4 - 23°C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
7664-38-2	Orthophosphoric acid	-	1		TWA (8 h)	WEL
		-	2		STEL (15 min)	WEL

8.2. Exposure controls

Protective and hygiene measures

When using do not eat, drink or smoke.

Eye/face protection

Framed glasses.

Hand protection

Single-use gloves.

Skin protection

Lab apron.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Jelly Colour: blue

Test method

pH-Value: <1

Changes in the physical state

Density (at 23 °C): 1.3 g/cm³ Water solubility: easily soluble.

(at 23 °C)

Solubility in other solvents

Ethanol.

SECTION 10: Stability and reactivity

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.4. Conditions to avoid

Further information

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

Irritation and corrosivity

Causes severe skin burns and eye damage.

Sensitising effects

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

SECTION 12: Ecological information

12.1. Toxicity

CAS No	Chemical name								
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method			
7664-38-2	Phosphoric acid	Phosphoric acid							
	Acute fish toxicity	LC50 138 mg/l	1	Gambusia affinis (Mosquito fish)					

Further information

Do not allow uncontrolled leakage of product into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number: UN 1805

14.2. UN proper shipping name: PHOSPHORIC ACID SOLUTION

14.3. Transport hazard class(es): 8 Ш 14.4. Packing group: Hazard label: 8 Classification code: C1 Limited quantity: 5 L Excepted quantity: E1 Transport category: 3 Hazard No: 80 Tunnel restriction code: Ε

Other applicable information (land transport)

: 3 E

Inland waterways transport (ADN)

<u>14.1. UN number:</u> ---

Marine transport (IMDG)

14.1. UN number: UN 1805



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14.2. UN proper shipping name: PHOSPHORIC ACID SOLUTION

14.3. Transport hazard class(es):814.4. Packing group:IIIHazard label:8Special Provisions:223Limited quantity:5 LExcepted quantity:E1EmS:F-A. S-B

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: UN 1805

14.2. UN proper shipping name: PHOSPHORIC ACID SOLUTION

14.3. Transport hazard class(es):814.4. Packing group:IIIHazard label:8Special Provisions:A3 A803Limited quantity Passenger:1 LPassenger LQ:Y841Excepted quantity:E1

IATA-packing instructions - Passenger: 852
IATA-max. quantity - Passenger: 5 L
IATA-packing instructions - Cargo: 856
IATA-max. quantity - Cargo: 60 L

Other applicable information (air transport)

60 L

SECTION 15: Regulatory information

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

EU regulatory information

Additional information

Classification according to Regulation (EC) No 1272/2008 [CLP]

National regulatory information

SECTION 16: Other information

Relevant H and EUH statements (number and full text)

H314 Causes severe skin burns and eye damage.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal.

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



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

1.1. Product identifier

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

Use of the substance/mixture

for dental use only

1.3. Details of the supplier of the safety data sheet

Company name: COLTENE/Whaledent AG Street: Feldwiesenstrasse 20 Place: CH-9450 Altstätten +41 (71) 75 75 300 Telephone: Telefax: +41 (71) 75 75 301 e-mail: info.ch@coltene.com Internet: www.coltene.com Responsible Department: Regulatory Affairs

msds@coltene.com

1.4. Emergency telephone +41 (0) 44 251 51 51 - Tox Info Suisse (24 h)

number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Flammable liquid: Flam. Liq. 3 Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2 Respiratory or skin sensitisation: Skin Sens. 1

Hazard Statements:

Flammable liquid and vapour.

Causes skin irritation.

May cause an allergic skin reaction. Causes serious eye irritation.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

2-hydroxyethyl methacrylate

Signal word: Warning

Pictograms:





Hazard statements

H226 Flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.



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P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

Additional advice on labelling

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name	Chemical name					
	EC No	Index No	REACH No				
	Classification according to Regulat	ion (EC) No. 1272/2008 [CLP]	•				
64-17-5	ethanol, ethyl alcohol			35 - < 40 %			
	200-578-6	603-002-00-5					
	Flam. Liq. 2; H225						
72869-86-4	Urethane dimethacrylate			20 - < 25 %			
	276-957-5						
	Aquatic Chronic 3; H412						
868-77-9	2-hydroxyethyl methacrylate			5 - < 10 %			
	212-782-2	607-124-00-X					
	Eye Irrit. 2, Skin Irrit. 2, Skin Sens.	1; H319 H315 H317					

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: Water and soap.

After contact with eyes

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

After ingestion

Seek medical advice.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water spray. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.

Additional information

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

SECTION 6: Accidental release measures



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6.1. Personal precautions, protective equipment and emergency procedures

Remove all sources of ignition. Provide adequate ventilation. Remove persons to safety.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated areas thoroughly.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid contact with skin and eyes.

for professional use only Keep out of the reach of children.

Observe instructions for use.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking.

Further information on handling

After use replace the closing cap immediately.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and in a well-ventilated place.

Further information on storage conditions

Recommended storage temperature: 4 - 8 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

8.2. Exposure controls

Protective and hygiene measures

When using do not eat, drink or smoke.

Eye/face protection

Framed glasses.

Hand protection

Single-use gloves.

Skin protection

Lab apron.

Respiratory protection

Provide adequate ventilation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: liquid
Colour: light yellow



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Odour: characteristic

Test method

Changes in the physical state

Flash point: 28 °C

Density: 1.0 g/cm³

Water solubility: partially soluble

Solubility in other solvents

Ethanol.

SECTION 10: Stability and reactivity

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.4. Conditions to avoid

heat.

10.5. Incompatible materials

Oxidizing agents.

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	Chemical name								
	Exposure route	Dose		Species	Source	Method				
64-17-5	ethanol, ethyl alcohol									
	oral	LD50 mg/kg	6200	Rat	IUCLID					
	inhalative (4 h) vapour	LC50	95,6 mg/l	Rat	RTECS					
72869-86-4	Urethane dimethacrylate									
	oral	LD50 mg/kg	>2000	Rat		OECD 401				
868-77-9	2-hydroxyethyl methacrylate									
	oral	LD50 mg/kg	5050	Rat						

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (2-hydroxyethyl methacrylate)

SECTION 12: Ecological information

12.1. Toxicity



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CAS No	Chemical name	Chemical name							
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method		
64-17-5	ethanol, ethyl alcohol	ethanol, ethyl alcohol							
	Acute crustacea toxicity	EC50 9	9268 -	48 h	Daphnia magna	IUCLID			
72869-86-4	Urethane dimethacrylate								
	Acute fish toxicity	LC50 mg/l	10.1		Brachydanio rerio (zebra-fish)		OECD 203		
868-77-9	2-hydroxyethyl methacryla	2-hydroxyethyl methacrylate							
	Acute fish toxicity	LC50 2	227 mg/l	96 h	Pimephales promelas				

12.2. Persistence and degradability

CAS No	Chemical name						
	Method	Value	d	Source			
	Evaluation						
72869-86-4	Urethane dimethacrylate						
	OECD 301 F	22%	28				
	Product is not easily biodegradable.						

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
64-17-5	ethanol, ethyl alcohol	-0,31
72869-86-4	Urethane dimethacrylate	3.39
868-77-9	2-hydroxyethyl methacrylate	0,47

Further information

According to the criteria of the EC-classification and labelling "dangerous for the environment" (93/21/EEC) the material/product is not to be classified as dangerous to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number: UN 1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es):314.4. Packing group:IIHazard label:3Classification code:F1Limited quantity:LQ4Hazard No:33

Other applicable information (land transport)

Special provisions: 274

E3



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: 1 D/E

Special provisions: 274 601 640C

E2 : 2

Special provisions: 640C Special provisions: 144 601

Marine transport (IMDG)

14.1. UN number: UN 1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

 14.3. Transport hazard class(es):
 3

 14.4. Packing group:
 II

 Hazard label:
 3

 Limited quantity:
 3 L

 EmS:
 F-E, S-D

Other applicable information (marine transport)

Special provisions: 274, 330, 944 Special provisions: 944 Special provisions: 144, 330

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: UN 1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es):314.4. Packing group:IIHazard label:3Limited quantity Passenger:1 L

IATA-packing instructions - Passenger: 305
IATA-max. quantity - Passenger: 5 L
IATA-packing instructions - Cargo: 307
IATA-max. quantity - Cargo: 60 L

Other applicable information (air transport)

E2 : Y305 60 L

SECTION 15: Regulatory information

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

National regulatory information

Additional information

SECTION 16: Other information

Relevant H and EUH statements (number and full text)

H225 Highly flammable liquid and vapour. H226 Flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.



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Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal.

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