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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 4

Revision: 12.09.2017

SECTION 1: Identification

- · 1.1 Product identifier
- · Trade name: Coe Soft Liquid
- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Auxiliary for dental technology
- \cdot 1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier: GC EUROPE N.V. Interleuvenlaan 33 B-3001 Leuven Tel. +32/(0)16/74.10.00 Fax +32/(0)16/40.26.84 msds@gc.dental

· Information department: Regulatory affairs

· 1.4 Emergency telephone number: International: +01-813-248-0585 (ChemTel Inc.)

SECTION 2: Hazard(s) identification

· 2.1 Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 2 H371 May cause damage to organs.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device. The product is classified and labeled according to the CLP regulation.

· Hazard pictograms



· Signal word Danger

Hazard-determining components of labeling: Benzyl salicylate
Peppermint oil
Hazard statements
H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H371 May cause damage to organs.

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(Contd. of page 1) · Precautionary statements Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No P210 smoking. P260 Do not breathe dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P405 Store locked up. P501 Dispose of contents/container in accordance with local/regional/national/international regulations. · 2.3 Other hazards

· Results of PBT and vPvB assessment

• *PBT:* Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterization: Mixtures

· Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

· Dangerous components:			
118-58-1	Benzyl salicylate	25-<50%	
	STOT SE 2, H371; Eye Irrit. 2, H319; Skin Sens. 1, H317		
64-17-5	ethyl alcohol	10-<25%	
	Flam. Liq. 2, H225		
	Peppermint oil	1%	
	Flam. Liq. 3, H226; Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Skin Sens. 1, H317		
• Additional information: For the wording of the listed hazard phrases refer to section 16.			

SECTION 4: First-aid measures

· 4.1 Description of first aid measures

· General information:

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

• After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

• *After skin contact: Immediately wash with water and soap and rinse thoroughly.*

Seek medical treatment.

If skin irritation continues, consult a doctor.

• After eye contact:

Protect unharmed eye.

Rinse opened eye for several minutes under running water. Then consult a doctor.

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• After swallowing:

Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.

• 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions

• 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Fire-fighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- · 5.2 Special hazards arising from the substance or mixture
- Formation of toxic gases is possible during heating or in case of fire.
- · 5.3 Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

· Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures *Remove persons from danger area.* Keep away from ignition sources Avoid contact with the eyes and skin. Wear protective clothing. · 6.2 Environmental precautions: Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to penetrate the ground/soil. In case of seepage into the ground inform responsible authorities. 6.3 Methods and material for containment and cleaning up: Ensure adequate ventilation. Absorb liquid components with liquid-binding material. Dispose of the collected material according to regulations. · 6.4 Reference to other sections See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols. Avoid contact with the eyes and skin.
Information about protection against explosions and fires: Keep ignition sources away - Do not smoke. Protect against electrostatic charges. Do not spray on a naked flame or any incandescent material.

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Storage:
Requirements to be met by storerooms and receptacles: Store in a cool location. Store only in unopened original receptacles.
Information about storage in one common storage facility: Store away from foodstuffs.
Further information about storage conditions: Keep receptacle tightly sealed. Store in cool, dry conditions in well sealed receptacles. Protect from heat and direct sunlight. Store in a cool place.
7.3 Specific end use(s) No further relevant information available.

• Additional information about design of technical systems: No further data; see item 7.

· 8.1 Control parameters

· Components with limit values that require monitoring at the workplace:

· 7.2 Conditions for safe storage, including any incompatibilities

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

• Additional information: The lists that were valid during the creation were used as basis.

· 8.2 Exposure controls

- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed. Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing.

· Breathing equipment: Suitable respiratory protective device recommended.

· Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

• Eye protection:



Tightly sealed goggles

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9.1 Information on basic physical a	und chemical properties	
General Information		
Appearance:		
Form:	Liquid	
Color:	Clear	
Odor: Odor threshold:	Characteristic Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/Melting range:	Undetermined. 173 °C	
Boiling point/Boiling range:	Undetermined.	
Flash point:	13 °C Not applicable	
	Not applicable.	
Flammability (solid, gaseous):	Not applicable.	
Ignition temperature:	Undetermined.	
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	3.5 Vol %	
•	Not determined.	
Upper:	15 Vol % Not determined.	
Vapor pressure:	Not determined.	
Density at 20 °C:	$1.04 \ g/cm^3$	
	Not determined.	
Relative density	Not determined.	
Vapor density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with	Incoluble	
Water:	Insoluble.	
Partition coefficient (n-octanol/wat	ter): Not determined.	
Viscosity:		
Dynamic at 20 °C:	34 mPas	
Kinematic:	Not determined. Not determined.	
	1101 ucie//////cu.	
Solvent content:	14 8 0%	
Organic solvents:	14.8 % 153.0 g/l	
VOC (EC) 9.2 Other information	153.9 g/l No further relevant information available.	

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SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- Acute toxicity: Based on available data, the classification criteria are not met.

· LD/LC50 values that are relevant for classification:

64-17-5 ethyl alcohol

LD50 7,060 mg/kg (rat (f+m))

Inhalative LC50/4 h 20,000 mg/l (rat (f+m))

- · Primary irritant effect:
- on the skin: Based on available data, the classification criteria are not met.
- on the eye:

Oral

- Causes serious eye irritation.
- · Sensitization:
- May cause an allergic skin reaction.
- · Additional toxicological information:

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

- *Repeated dose toxicity No further relevant information available.*
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure
- May cause damage to organs.
- · 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.

SECTION 12: Ecological information

· 12.1 Toxicity

- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- Remark: Toxic for fish
- Additional ecological information:
- · General notes:
- Also poisonous for fish and plankton in water bodies.

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Toxic for aquatic organisms

Water hazard class 2 (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.

· 12.5 Results of PBT and vPvB assessment

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

· 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 00 00 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)

18 01 00 wastes from natal care, diagnosis, treatment or prevention of disease in humans

18 01 06* chemicals consisting of or containing hazardous substances

· Uncleaned packagings:

• *Recommendation: Disposal must be made according to official regulations.*

· 14.1 UN-Number · ADR, IMDG, IATA	UN1993
	011775
· 14.2 UN proper shipping name · DOT	Flammable liquids, n.o.s. (Ethanol, Isopropanol)
ADR	1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTIO)
	ISOPROPYL ALCOHOL), special provision 640D
· IMDG, IATA	FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTIO
1,110,1111	ISOPROPYL ALCOHOL)
ADR	
· Class	3 (F1) Flammable liquids
Label	3

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Version number 4 Printing date 03.08.2018 Revision: 12.09.2017 Trade name: Coe Soft Liquid (Contd. of page 7) · IMDG, IATA · Class 3 Flammable liquids · Label 3 · 14.4 Packing group II· ADR, IMDG, IATA · 14.5 Environmental hazards: · Marine pollutant: No Warning: Flammable liquids · 14.6 Special precautions for user · Danger code (Kemler): 33 · EMS Number: F-E, S-E· Stowage Category В · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable. · Transport/Additional information: $\cdot ADR$ \cdot Limited quantities (LQ) lL· Excepted quantities (EQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml · Transport category 2 • Tunnel restriction code D/E· IMDG \cdot Limited quantities (LQ) lLCode: E2 • Excepted quantities (EQ) Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL · UN "Model Regulation": PROVISION 640D (ETHANOL SOLUTION, ISOPROPYL ALCOHOL), 3, II

SECTION 15: Regulatory information

 \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture \cdot Sara

· Section 355 (extremely hazardous substances):

None of the ingredient is listed.

• Section 313 (Specific toxic chemical listings):

67-63-0 isopropyl alcohol

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· Proposition 65	
• Chemicals known to cause cancer:	
None of the ingredients is listed.	
• Chemicals known to cause reproductive toxicity for females:	
None of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for males:	
None of the ingredients is listed.	
Chemicals known to cause developmental toxicity:	
64-17-5 ethyl alcohol	
Carcinogenic categories	
EPA (Environmental Protection Agency)	
None of the ingredients is listed.	
TLV (Threshold Limit Value established by ACGIH)	
64-17-5 ethyl alcohol	A3
67-63-0 isopropyl alcohol	A4
MAK (German Maximum Workplace Concentration)	
64-17-5 ethyl alcohol	5
NIOSH-Ca (National Institute for Occupational Safety and Health)	·
None of the ingredients is listed.	

• *Directive 2012/18/EU*

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· Seveso category P5c FLAMMABLE LIQUIDS

• Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

• Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

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.

H371 May cause damage to organs.

H411 Toxic to aquatic life with long lasting effects.

· Classification according to Regulation (EC) No 1272/2008 Calculation method

· Department issuing SDS: Regulatory affairs

· Contact: msds@gc.dental

• 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

DOT: US Department of Transportation

IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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ACGIH: American Conference of Governmental Indus	
EINECS: European Inventory of Existing Commercial	
ELINCS: European List of Notified Chemical Substant	ces
CAS: Chemical Abstracts Service (division of the American	rican Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)	
LC50: Lethal concentration, 50 percent	
LD50: Lethal dose, 50 percent	
PBT: Persistent, Bioaccumulative and Toxic	
vPvB: very Persistent and very Bioaccumulative	
NIOSH: National Institute for Occupational Safety	
OSHA: Occupational Safety & Health	
Flam. Liq. 2: Flammable liquids – Category 2	
Flam. Liq. 3: Flammable liquids – Category 3	
Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Categ	2
Skin Sens. 1: Skin sensitisation – Category 1	ory 2
STOT SE 2: Specific target organ toxicity (single expo	sure) = Category 2
Aquatic Chronic 2: Hazardous to the aquatic environm	
· Sources	
• ECHA (http://echa.europa.eu/)	
• EnviChem (www.echemportal.org)	
$\cdot *$ Data compared to the previous version al	tered.
This version replaces all previous versions.	
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	ability in connection with the use of this information or the products
	ned by the purchaser/user. The information contained herein is also
	avoidance of doubt, however, nothing in this document excludes or
limits our liability for death or personal inju	ry caused by our negligence or for fraudulent misrepresentation.
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