Revision: 07.02.2024



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

Printing date 07.02.2024

Version number 3 (replaces version 2)

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

- · 1.1 Product identifier
- · Trade name: COE-PAK Base (AUTOMIX NDS)
- 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
- · 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

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: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Eye Dam. 1 H318 Causes serious eye damage.

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

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labeled according to the CLP regulation.

· Exemptions

The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).

· Hazard pictograms





GHS05

GHS07

- · Signal word Danger
- · Hazard-determining components of labeling:

Lauric acid

Resin G

· Hazard statements

H318 Causes serious eye damage.

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

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· Precautionary statements

P272 Contaminated work clothing must not be allowed out of the workplace.

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. P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Additional information:

4.3 % of the mixture consists of component(s) of unknown toxicity.

Contains 4.3 % of components with unknown hazards to the aquatic environment.

- · 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	s components:		
143-07-7	Lauric acid	Eye Dam. 1, H318	10-<25%
9000-75-3	Resin G	Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Skin Sens. 1, H317	2.5-<5%
89-68-9	6-chlorothymol	Skin Irrit. 2, H315	1-<2.5%

[·] 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.

Call a doctor immediately.

· After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

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- · 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: Firefighting 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.

No further relevant information available.

- · 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.

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:

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 eves and skin.

- · Information about protection against explosions and fires: Protect against electrostatic charges.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: 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.

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· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Components with limit values that require monitoring at the workplace:

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
- Additional information about design of technical systems: No further data; see section 7.
- · 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.

Keep away from foodstuffs, beverages and feed.

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

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information

· Physical state Fluid

· Color: According to product specification

· Odor: Odorless

· Odor threshold: Not determined. · Melting point/Melting range: Undetermined.

Boiling point/Boiling range:
 Flammability (solid, gaseous):
 Undetermined.
 Not applicable.

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	(Contd. of page
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Auto igniting:	Undetermined.
Decomposition temperature:	Not determined.
pH-value:	Not determined.
Viscosity:	
Kinematic:	Not determined.
Dynamic at 20 °C:	162 mPas
Solubility in / Miscibility with	
Water:	Insoluble.
Partition coefficient (n-octanol/water):	Not determined.
Vapor pressure:	Not determined.
Density and/or relative density	
Density at 20 °C:	1 g/cm^3
Relative density	Not determined.
Vapor density	Not determined.
<u> </u>	1,00 0000,0000
9.2 Other information	
Appearance:	
Form:	Pasty
Important information on protection of hea	lth and
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Solvent content:	
Organic solvents:	0.8 %
Water:	0.8 %
VOC (EC)	$8.3 \ g/l$
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard cla	5505
Explosives	Void
Flammable gases	Void Void
Aerosols	Void Void
	Void Void
Oxidising gases	void Void
Gases under pressure	
Flammable liquids Flammable solids	Void Void
	Void Void
Self-reactive substances and mixtures	Void V.: 1
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammab	
in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void

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· Desensitised explosives

Void

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: No further relevant information available.
- · on the skin: Based on available data, the classification criteria are not met.
- · on the eye: Causes serious eye damage.
- · Sensitization: May cause an allergic skin reaction.
- · 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.
- · Specific target organ toxicity single exposure Based on available data, the classification criteria are not met.
- · Specific target organ toxicity 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 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)

No further relevant information available.

- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

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.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

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- · 12.7 Other adverse effects
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

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.

Harmful to aquatic organisms

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	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)		
18 01	wastes from natal care, diagnosis, treatment or prevention of disease in humans		
18 01 0	6* chemicals consisting of or containing hazardous substances		

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

14.1 UN-Number		
ADR, ADN, IMDG, IATA	not regulated	
14.2 UN proper shipping name		
DOT, ADR, ADN, IMDG, IATA	not regulated	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	not regulated	
14.4 Packing group		
ADR, IMDG, IATA	not regulated	
14.5 Environmental hazards:		
Marine pollutant:	No	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Anno	ex II of	
MARPOL73/78 and the IBC Code	Not applicable.	

EU

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SECTION 15: Regulatory information	
15.1 Safety, health and environmental regulations/legislation specific for the substance or mix Sara	cture
Section 355 (extremely hazardous substances):	
None of the ingredient is listed.	
Section 313 (Specific toxic chemical listings):	
None of the ingredients is listed.	
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)	
64-17-5 ethyl alcohol	
67-63-0 isopropyl alcohol	
MAK (German Maximum Workplace Concentration)	
143-07-7 Lauric acid	
64-17-5 ethyl alcohol	
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. REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3	
DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances electronic equipment – Annex II	in electrical
None of the ingredients is listed.	
REGULATION (EU) 2019/1148	
Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of Article 5(3))	of licensing un
None of the ingredients is listed.	
Annex II - REPORTABLE EXPLOSIVES PRECURSORS	
None of the ingredients is listed.	

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· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

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
- · Date of previous version 28.06.2023
- · Version number of previous version: 2
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American 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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

 ${\it Skin Sens. 1: Skin sensitisation-Category 1}$

 $\label{lem:aquatic chronic 2: Hazardous to the aquatic environment - long-term\ aquatic\ hazard-Category\ 2$

 $\label{lem:aquatic Chronic 3: Hazardous to the aquatic environment - long-term\ aquatic\ hazard-Category\ 3$

· Sources

- ECHA (http://echa.europa.eu/)
- EnviChem (www.echemportal.org)
- · * Data compared to the previous version altered.

This version replaces all previous versions.

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